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TOXIC SUBSTANCES CONTROL ACT OVERSIGHT

HEARINGS

BEFORE THE

SUBCOMMITTEE ON TOXIC SUBSTANCES AND
ENVIRONMENTAL OVERSIGHT

OF THE

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ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

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TOXIC SUBSTANCES CONTROL ACT OVERSIGHT

WEDNESDAY, JULY 27, 1983

U.S. Senate,
Committee on Environment and Public Works,
Subcommittee on Toxic Substances and
Environmental Oversight,
Washington, D.C.

The subcommittee met, at 10:13 a.m., in room SD-406, Dirksen Senate Office Building, Hon. Dave Durenberger (chairman of the subcommittee) presiding.

Present: Senators Durenberger, Stafford, and Humphrey.

OPENING STATEMENT OF HON. DAVE DURENBERGER, U.S. SENATOR FROM THE STATE OF MINNESOTA

Senator **Durenberger**. The hearing will come to order.

I apologize for the delay, and I will have more to say about delays in this series of hearings at the end of my statement. The Senate was invited to discuss Central America with the Secretary of State and the President's National Security Adviser, and I attended the first half hour of that and came away with the feeling I am not sure which is the greater danger to the health of the American people, Central America or toxic substances.

Today is the first in a series of oversight hearings on toxic substances, a rather broad field, and an area in which we have specific jurisdiction, the Toxic Substances Control Act. These hearings will be held by the subcommittee over the next few days. There is no specific legislative proposal before us.

Earlier this year, the Environment and Public Works Committee reported a simple reauthorization of TSCA. Authorizations under the act expire on September 30. Although a simple reauthorization is now on the Senate Calendar, these hearings may lead us to substantive amendments either in this session of Congress or the next.

So our purpose in the next few days is primarily educational. We will cover the whole range of toxic substance issues. Is enough information included in the premanufacture notices? Should PMN requirements under TSCA be coordinated with notification provisions adopted by the European Community? Does TSCA unduly discourage innovation in the chemical industry? Should EPA apply significant new use rules more often? How does TSCA relate to other regulatory programs including FIFRA, OSHA, and the Consumer Product Safety Commission?

There will be a great temptation to reduce this discussion to acronyms, section numbers, and hyphenated, multisyllable names for exotic chemicals. I hope the witnesses will not yield to that kind of temptation. The real question is not how many 5(e) notices have been issued, but whether or not risks to human health and the environment are being recognized soon enough and managed well enough.

There are two fundamental parts of TSCA, the new chemicals program and the program for existing chemicals. Each has a critical element which must be working if TSCA is to meet the goal of reducing risk. In the case of the new chemical program, the critical element is structural activity relationship analysis, the so-called SAR process conducted by EPA. If SAR is not working, if it is not managed well or is not doable even when managed well, then the new chemical program, as designed by TSCA, will not be successful, and we should look for some other approach.

For existing chemicals, the critical element appears to be the Interagency Testing Committee and the series of events that an ITC listing triggers. Again, if the ITC process does not work, it is unlikely that society and the environment are being adequately protected from the risks of chemicals already in use.

To give some clue to the witnesses and the public, it appears to me that SAR and ITC are not working well. They are weak links in the process, critical elements that raise serious questions. If my concerns are confirmed by this hearing, I will recommend amendments to TSCA for consideration by this subcommittee.

The business item that I need to take care of before we turn to the witnesses is that because of the prolonged markup yesterday, we have been forced to postpone tomorrow's hearing so that the full committee can conclude the markup on RCRA. Some of the witnesses scheduled for tomorrow will be scheduled for Friday, and the panel of witnesses representing the chemical industry and the environmental community will appear on next Monday at 10 a.m. I know some of them are in the room today.

I welcome all of you here. I welcome in advance the contributions that each of the witnesses has made to this subject area and the reputations that you have rightfully earned in this field, the work you have put into your statements.

I will indicate in advance that your full, printed statements will be made part of the record, and I will call on the first panel, Dr. John F. Finklea, professor, Department of Preventative Medicine, University of Alabama, Birmingham, Ala.; Dr. Theodore J. Kneip, professor, deputy director, Laboratory for Environmental Studies, New York University Medical Center, Institute of Environmental Medicine, New York University, New York, N.Y., and graduate of the University of Minnesota; and Dr. William E. Cooper, Department of Zoology, Michigan State University, College of Natural Sciences, Michigan State.

I suggest that after you have summarized your statements, that you feel as relaxed as possible in this environment. I indicated in my opening comments that this is an educational process. It will be helpful to the record of this hearing if you are able not only to respond to the questions that you might receive from members of the subcommittee but if you would be willing to react when we get into discussions to some of the comments made by your colleagues.

You have been deliberately asked to come here and testify not down a single track but down different tracks. So to the degree you want to comment on testimony of your colleagues, I think the record of this hearing will be better for that reaction. So if we may begin first in the order you were introduced. Dr. Finklea.

STATEMENT OF JOHN F. FINKLEA, PROFESSOR, DEPARTMENT OF PREVENTATIVE MEDICINE, UNIVERSITY OF ALABAMA

Dr. FINKLEA. Thank you, Mr. Chairman. I will summarize rather than reading the entire statement.

As I said in my statement, I worked for 10 years in the Federal Government before returning to teaching in the medical school and School of Public Health of the University of Alabama in Birmingham. I spent several days in the past over here with various committe staff who developed the toxic substances legislation. I didn't work directly with the Toxic Substances Control Act, but I was often interested in some of the problems that the law addressed.

I do recall clearly several hopes which we had for the legislation. The first problem we hoped would be dealt with is the premarketing assessment of the industrial commercial chemicals, to decide whether or not marketing would pose a substantial degree of risk or adverse effect on either the environment or public health.

The second group of problems we hoped would be covered related to the safe use of commercial and industrial substances, especially chemicals. This latter group of considerations could also be viewed as a way to take care of problems which were not dealt with very well in other environmental laws or in other health and safety legislation. At least one person I knew here in Washington referred to this as a "tidying up" of other legislation.

When thinking about the first group of problems dealing with premarketing assessments, I would like to just give you two examples we worried about at that time.

In the late 1960's, a chemist friend of mine was demonstrating to me the techniques for measurement of residues of chlorinated hydrocarbon pesticides in human sera collected from groups of workers exposed to pesticides and in human sera from the general population. After we covered the sample preparation techniques then used, he pointed out the residue chromatography peaks associated with some of the commonly used pesticides. I asked what might be responsible for a number of other peaks noted in sera from the general population. We did some work and it turned out that these peaks were associated with polychlorinated byphenyls and that we had stumbled on one of the first bits of evidence that PCB residues in humans were widespread and might pose a health risk. Not too much was known about the persistence of PCB's in the environment or their long-term effects on health at that time. PCB's were viewed as exceedingly useful compounds that provided, among other things, a beneficial degree of fire protection in transformers housed on or in buildings rather than as a material whose continued use would cause wide dissemination through the environment, threats to wildlife and concern about public health. We all hoped that the Toxic Substances Control Act could prevent a recurrence of this kind of a problem. I don't know of a problem quite that large or that pervasive what has occurred since the toxic substances legislation was enacted. We also didn't have a problem quite that large during the 5 or 6 years before TSCA was enacted.

A second example, during the late 1960's and early 1970's, we were concerned about a number of environmental contamination and environmental health problems, including use of products that contained releasable asbestos and the accumulation of cadmium from various sources in the renal cortex of man. The asbestos problem has since that time grown into a major public health and legal issue with which you are probably quite familiar.

The cadmium problem hasn't received too much attention. Our concern about cadmium was primarily based upon the realization of autopsy studies in industrialized countries showed that there was widespread accumulation of cadmium in the renal cortex to a level not far below that which was associated with altered kidney function. Cadmium exposures involve food, cigarette smoke, some occupations and, to a lesser extent, pesticides, sewage sludge and drinking water. I am not sure the Toxic Substances Control Act has helped us very much with either the asbestos or the cadmium problem.

Turning now to a more diverse second grouping of problems, I would like to call your attention to several.

At the time the act was passed, we didn't have a good system for sharing information dealing with pesticides among several Federal agencies responsible for health and safety research or regulation. This extended to other materials, especially trade secret materials, that had been submitted to one Federal agency.

There is a gentleman in the hearing room today, Ed Johnson, who about that time TSCA was passed or shortly after worked out a system whereby those Federal officials who needed access to protect health and safety could have access to this information. This has been worked out very well. I think the debate dealing with TSCA had a lot to do with this problem being resolved. We still have a problem getting the same trade secret information dealing with pesticides to our colleagues in other countries who are responable for health and safety matters.

Another problem which we were having was that there were occasionally allegations that industry destroyed records needed for health studies of the long-term effects of chemical exposures. Industry felt these allegations were unjustified, saying that old, inactive personnel and medical records were routinely destroyed after varying periods of time. It costs money to keep these records for several decades. I believe the Toxic Substances Control Act, and subsequent OSHA regulations promulgated under another law, have dealt pretty well with this records retention problem.

The third problem was Federal right of entry to conduct workplace studies and for study of personnel and health records of current and past employees. This right of entry was being exercised under other legislation and was being contested in the courts. This matter was also addressed by the Toxic Substances Control Act, and, it seems to me, in the years since the act was passed, we now have the degree of access which is required for our Federal officials.

A fourth problem was that we didn't have any early warning system for newly emerging health problems. It wasn't clear what were the ethical and legal responsibilities of health personnel working for the private sector. For example, problems arising during the manufacture of leptophos and concern about the carcinogenicity of vinyl chloride monomer were not revealed in a timely fashion. Others have alleged that there were similar disclosure delays with information involving adverse effects related to asbestos and dibromochloropropane. It was generally agreed that there was need for an effective early warning system. Reporting of newly observed adverse health effects, as required by the Toxic Substances Control Act, has, in my opinion, been quite helpful.

We have a system set up where everybody knows what the legal and ethical rules are for newly emerging problems, and I think people observing it feel it has been fair and useful.

A fifth problem was that industrial and commercial chemicals were often poorly labelled and that it was difficult to disentangle what chemicals might be present in a commercial formulation containing several trade name products of uncertain composition. Needless to say, the materials safety data sheets for these products, if they were available, were often not very helpful. Without basic information of this sort, it is pretty difficult for the small employer to protect himself and his employees. This labeling failure and the incomplete materials safety data sheets remain a major problem in educating employers and employees. I personally have always felt that workers had a "right to know" what they were exposed to and the extent of such exposures. It really boils down to a "how in the heck do you find out" problem which is still very much with us.

A sixth problem was how to get a better assessment of the chronic effects of repeated short- or long-term exposures to chemicals already being marketed. A mechanism was set up whereby an interagency committee could recommend to the EPA Administrator what chemicals should be tested by industry. The committee has made a number of recommendations to which EPA eventually replied in the Federal Register.

However, it doesn't seem to me that EPA required industry to do very much in this matter. The chemical industry itself organized a facility to conduct toxicologic testing of a number of the industrial chemicals used in large quantities throughout the industry. This may or may not have happened without the toxic substance legislation. At any rate, it doesn't seem to me the act has worked very effectively in getting the needed testing of chemicals already on the market.

A seventh problem of major concern was the effects on reproduction of commercial and industrial chemicals. We didn't then and don't now have enough information on the effects of commercial and industrial chemicals on human reproduction. We have spent a fair amount of money on testing of materials for carcinogenicity and other effects. We don't have a handle on reproductive effect of chemicals, other than pesticides, and it is a major problem in our society. I get calls from doctors wanting to know whether or not people should continue to work during pregnancy. I wish we had better answers for them.

An eighth problem was we didn't really know very much about the health hazards of chemicals produced primarily for export, like kepone and leptophos, or chemicals imported into this country. I really don't know whether or not EPA has established a good system to deal with these problems. I do know that countries which import chemicals from the United States would like to have a reliable source of information other than information from the companies who directly benefit from sales of these products.

The problem here is that much of the information submitted to EPA is trade secret and has not been shared internationally.

There is another set of concerns never far from sight and very difficult to resolve. Basically these involve how do you prevent legislation and regulation from making presumptions that cannot be supported scientifically. These often have to do with assessments of risk or defining what is a risk to health. Likewise, how do you develop regulations, especially those dealing with toxicologic testing, that do not tend to freeze us into the acceptance of less than adequate methodology when better test methods may become available in the near future. We certainly have better short-term test methods than we had 10 years ago. Federal regulation tends to get stuck once it gets in there. I certainly would hope we can have a system whereby we can take advantage of advances in methods of toxicologic testing.

One additional topic that those still in Government, including some of my EPA colleagues in the second row of this room might not want to discuss candidly with you the matter of adequate funding to implement environmental laws and legislation dealing with health and safety. I myself have been up here before Congress as a representative of two of those agencies. As we all know, Federal officals have to get their testimony cleared by the Office of Management and Budget. It often seemed to me that the legislative branch of government passed legislation that could not be implemented with the resources which were made available to the executive branch. I think we need a much closer look at what is required. There may be reasons for allowing such a mismatch between requirements and resource to occur, but the tendency to do so undermines trust and faith in our Federal Government. Those responsible for implementing the legislation sometimes take a cynical view of the disparity between legislative requirements and the resources made available. Certainly this seems to have been a problem with the Toxic Substances Control Act.

Mr. Chairman, I hope these remarks are of some assistance to you and the subcommittee. I will be pleased to answer any questions you have.

Senator **Durenberger**. Thank you very much. Dr. Kneip.

STATEMENT OF PROF. THEODORE J. KNEIP, DEPUTY DIRECTOR, LABORATORY FOR ENVIRONMENTAL STUDIES, NEW YORK UNIVERSITY MEDICAL CENTER, INSTITUTE OF ENVIRONMENTAL MEDICINE

Dr. **Kneip**. Thank you. I appreciate the opportunity to come here and offer you my thoughts on toxic materials in the environment. I will not emphasize the TSCA act itself, but speak to a few problems I think exist that need attention. The problems I will address are those of contaminated aquatic sediments, particularly sediments in the harbors of our country; the gaps, I believe, in the technology we are using to determine what toxic materials are present; and finally, the need for renewed emphasis to obtain a full understanding of these problems before we pick the "cure."

I was involved in the 1970's in a research program in Foundry Cove near Cold Spring, N.Y., which was concerned with the severe cadmium contamination of sediments, and I have been involved in commissions that considered the PCB problems in the Hudson River and the mercury problem in the New Jersey Meadowlands.

In each of these cases, we have sediments in our area in New York that are more contaminated than any other known sediments in the world. They have some problems and features in common. Each resulted from long-term, uncontrolled discharges or permitted discharges of toxic materials and, unfortunately, the sediments accumulated toxic materials which happened to be discharged at relatively low concentrations initially. The cadmium deposit was dredged without any significant improvement in the environmental situation. Both the PCB's and mercury deposits have been recommended for dredging, but no action has taken place as yet.

While it is unlikely we can leave the mercury where it is in Berry's Creek, for reasons specific to that case, there are other possibilities for the PCB's and the cadmium. There have been no serious health problems or environmental problems caused by these materials as yet. We do have some time to do something about them.

In the case of Berry's Creek, the water is so low in dissolved oxygen that there are no valuable food organisms present and no one can go fishing there and get himself contaminated with mercury. If sewage treatment improvements bring oxygen back to the water, we can have a serious situation.

In the other cases, the contamination of the striped bass in the Hudson is dropping off, and the cadmium contaminates only blueclaw crabs and is in a relatively small area. However, in the cases of the harbors, particularly in my experience with New York Harbor, we have vast areas of contaminated sediments, contaminated with a whole host of materials, toxic metals, PCB's and all kinds of things that we haven't even identified yet, and the worst problem of all, is that we don't know the sources. The information on sources is very sketchy. No one has begun to determine how much has come from industrial discharges, how much is coming from sewage discharges. We have estimates, but not solid data.

I believe one of the documents that you have, or certainly a reference to the document, has a recommendation that until the control of industrial discharges of toxic material in a thorough fashion is attained, we are still going to face the fact we will have discharges into our harbors even from the sewage treatment plants.

One of the things that appears to have happened is with enforcement of regulations on industrial discharges, that is, direct discharges, industries have simply hooked up to the sewage treatment systems. Subsequently, the regulations that require control at that point have not been well enforced. So the toxic materials that now go into the sewage treatment plants are passing through them and appearing either in the sludge or with the effluent, directly in the water system.

I would like to address a second point; the current strategies for control of toxic substances are based mainly on data obtained with what is known as gas chromatographic and mass spectrometic techniques. These are very powerful techniques, but depend on the substances that are measured being volatile. For those that are not volatile we have very little information, and the analytical techniques are not very good at the present time.

You will find many references in the literature to findings of toxicity or carcinogenicity in bioassay tests of fractions taken from environmental samples with no identification of the compounds responsible for those biological responses. Much of this is simply due to the fact materials causing the response will not go through the instrumentation that is popularly used for determining these materials.

I think that more pressing priorities and lack of recognition of this problem have prevented a focus on the discrepancy between the bioassay and chemical measurements. I think it is timely to review the potential health impacts which may be related to these unidentified substances and to determine the need for improved analytical screening systems.

Lastly, I would like to reemphasize the point that it is time to consider each new step in the light of developed knowledge about overall environmental cycles. Easy solutions to existing environmental contamination often are simply transfers from one discharge medium to another. We have often times seen the selection of the first cure causing a larger problem.

I will use as an example the Ocean Dumping Act which bans sludge dumping, particularly in the New York Bight, as of 1981. We are all well aware that has not stopped. The reason it hasn't stopped is basically the fact you can't burn the sludge, you will contaminate the air; you can't put it in the land, you will contaminate the land. It will be impossible to farm on land that has been treated with New York City sludge. The result is the least harmful answer at the moment, put the sludge in the ocean which has enormous dilution capacity. But that is not the overall answer.

The overall answer is to get the toxic materials out of the sludge. If the sludge didn't have toxic materials, you could use it for fertilizer, you could burn it or put it in the ocean without great harm to any one of the three.

Don't pick the cure unless you know what the overall result may be. Thank you, sir.

Senator **Durenberger**. Thank you very much. Dr. Cooper.

STATEMENT OF WILLIAM E. COOPER, DEPARTMENT OF ZOOLOGY, MICHIGAN STATE UNIVERSITY, COLLEGE OF NATURAL SCIENCES, CHAIRMAN OF THE MICHIGAN ENVIRONMENTAL REVIEW BOARD

Dr. **Cooper**. Thank you, Mr. Chairman.

I perceive the Michigan Environmental Review Board as a receiver of the services, not an administrator of the act. I will make my comments in that context. I was asked to put in perspective the climate in which TSCA was passed back in 1976. I was very much involved with two major episodes, one with kepone contamination in the James River. Kepone, a chlorinated insecticide, was intentionally dumped, some 60,000 to 80,000 pounds we estimated. The second one happened in my State of Michigan, the PBB's. That was put into the feedstock of dairy cattle and very rapidly went through the whole State.

Both of these episodes—in 1973 the PBB and kepone in 1971 to 1975 discharged at 80,000 pounds—both of these constitute a major, at the State level, social-economic-political disaster. It is very difficult for a Governor to respond to frightened people with no data for such a long period of time.

I think one of the things we learned in both of those episodes was there is a timelag from when you know of that problem and when the scientists can give you enough data to know the magnitude of it. That is why there is a great degree of uncertainty with everybody. The timelag in both situations were months and years. It was something like 12 months after we discovered the cattle had physical and behavioral deformities that we discovered the cause. The kepone situation is still oscillating back and forth. Both of those, during that period of time, had the dubious honors of being on "60 Minutes" in all of their gory details.

Shortly after that, of course, the TSCA was passed. I think there is quite a history of environmental legislation coming out under the guise of hysteria with the promise that this won't happen again. I think everybody perceived TSCA as promising that.

If you look at the aspects of TSCA that seem to be most functional from the point of view of actually doing something, I think the risk assessment is by far the most important. The problem we had with the kepone and PBB's is nobody spent money on research, nobody worried about setting tolerance levels, and then you had the timelag for science to come up with answers.

The one thing about risk assessment is you anticipate the problem ahead of time, collect the data, do the modeling, do the analysis, do the what-if type of questions prior to any problems. You might not need the data, but if you need it, it is there and you have got experts who can tell you what your choices are.

When you look at risk assessment, there are basically three major areas, and EPA probably spent most of their time and effort not on removing chemicals from the marketplace but trying to get a data base to justify taking that kind of regulatory action.

One is in terms of toxicity. All kinds of science is going on now in testing the various toxicities, acute and chronic. In most cases, you are dealing with priority pollutants. You can't test all 70,000 chemicals. You would end up with all the biochemists in this country doing that. You make judgments on structure and function. You have a priority. You spend your time getting money to gather the data on that first. We have some toxicity data; we always need more. We can always use better testing.

The second aspect is probably the weakest, what the actual exposure contamination does to the environment. We are currently initiating a $6 million study on dioxin in Michigan. Part of that is going to be a human health study for soft-tissue cancer. Even if you find statistically significant differences in cancer, we have no way of actually measuring the exposure to the various compounds and what it is that is causing it. It is probably by taking the data from the laboratory and applying it to field conditions, which is going to be most difficult.

It might be kind of humorous, for dioxin, you can't take blood samples or fat bodies out of humans. It is such a low-concentration chemical that it takes such a large amount, a cubic inch, of fat to measure it. Most people don't want to do that.

The last basic area is one of taking your laboratory data on toxicity, taking your environmental data on exposure rates, exposure concentrations, and actually calculating what the potential damage might be—how many dead bodies are you going to have, how many fish are going to be exterminated, et cetera.

There are a lot of computer models and a lot of statistical-based models, most based on assumptions, that we can sit here all day and pick holes in. You have to use animals that have been raised in the laboratories. We test one compound at a time. We know we are dealing with mixtures out of the environment. We can't use humans and direct test subjects. We have to use inbred strains of mice and hope the safety factor will cover the difference in genetics.

We can go right down through the whole list of things scientists have to do in order to get data that is even in the ball park and make some kind of adjustments by putting a safety factor in. Most safety factors are unvalidated, and we don't have direct comparsion capability to humans.

From my point of view, anyway, the job is not to accumulate all the things we don't know. Basically what they are doing is using the best science that exists. If you have to go in front of a court of law and defend an action of a tolerance level, it is difficult because there are all these assumptions and guesstimations. I don't know how we do it any better at this stage of the game.

That ties in, I think, with some of the things you are going to hear from industry about the uncertainties, the costs, the unnecessary burdens. If you don't know ahead of time, it is really going to be a major episode. I think those costs and uncertainties are real. There is no question about it. A big company like Dow has a big testing facility and does this in a fairly routine fashion. A lot of the ma-and-pa, one-product companies are not in the ball game when it comes to the bigger companies. I think when you are going to talk cost, you have to talk societal costs, the other way.

You know what the PBB and kepone was in monetary costs. The estimates to dredge the James River and various kinds of mitigation to tie up the kepone was between $3 and 13 billion, and none of the alternative technology that were recommended were either socially or ecologically acceptable.

In terms of the PBB, the State of Michigan has paid over $400 million already trying to put farmers back in business. The landfill where they stored a lot of the kepone is a No. 1 superfund site. With the kepone and PBB, we have no idea about the long-range human health effects. There is no way you can put that cost in an equation.

In every case, you are talking about an undercapitalized, small chemical industry, and as soon as something goes wrong, they go bankrupt and all these funds come from the public sector, not the private sector. Parent corporations should be liable for the damage caused by some independent spinoff. Life Sciences and Michigan Chemical, both these small companies are now bankrupt. That is an open loop in the system that keeps from having direct accountability for actions.

I think one recommendation could be made. If you look at the costs, and one in particularly in Michigan, we have adopted a position that is unique in the country so far. If it works, it will probably be more common. That position is going away from best available technology and basing our water quality standards on biological toxicity data, biological-based standards, not best available technology. We have done this for a number of reasons.

We have compounds, in fact Dow Chemical has nine compounds to be discharged in the Tittonbawassee River that are known carcinogens. We were asked to essentially come up with a process of determining what a social acceptable risk of exposure to a carcinogen in the public waters will be.

The data we used to do this is all the data that came out, basically, from TSCA. You talked about relationships between various kinds of environmental legislation. You are using basically the same biological risk assessment, toxicity, exposures, probability of fatality, so forth, that you use in TSCA, and we are using at the State level for water quality.

You can work out a tiered system where you can give industry a tradeoff. If all they can provide is a very rudimentary set of data—boiling point, some of the stuff which didn't cost them any money, for risk assessment you use a safety factor of 100,000. If that makes it economically unacceptable, then you go spend your money in getting some biological data, and use a safety factor of 1,000. If you still think that is too great, then basically you spend a little bit more money and go out and get data on direct species that live where your plant is, wildlife, brook trout, whatever it is going to be, get better data, more relevant to the actual place, and use a safety factor of 100.

If you want to get tricky, get direct human exposure data and use a safety factor of 10. There is a tradeoff that has to be made between the uncertainty and the amount of money to be spent to get the data base.

I think there are ways one can get a tradeoff; all the data we get everywhere versus focusing on what you really need the data for, where it really comes from.

I think there has been a lot of concerned environmental groups that EPA has not aggressively gone out and taken bad chemicals off the market. TSCA alone has done that. Chemicals that were high risk cost a lot to get the relevent data. Companies are dropping products on their own. It is not economically effective to even get the data.

I think myself the pure presence of TSCA has done an awful lot to get us to remove some of these toxic chemicals. Thank you.

Senator DURENBERGER. Thank you very much.

We are going to have to limit the time for questions. We have developed a long list of fairly specific questions for each of you. I am going to warn you ahead of time we are going to submit these to you in writing. As I indicated in the beginning, this is a long-term process, and based on what I just heard in your testimony, if I am getting any advice from you, it is to walk before we run and run before we run the marathons. So we do have the luxury in this particular hearing of not dealing with a specific piece of legislation, but dealing with both problems and opportunities. I intend to submit to each of you a variety of questions.

One of the things the three of you have in common, of course, is an experience base at both various levels of government and the private sector that is, to a degree, incident related. When I am not chairing this subcommittee, I chair another one called Intergovernmental Relations in which we deal with such esoteric subjects as the New Federalism, devolution and how do we get rid of the Federal Government and turn everything back to somebody else.

I have developed, during the course of a couple years of dealing with that subject, a sense that one of the things that is missing in our understanding from the Federal system is a basic sense of national purpose. I occasionally, in speeches, read to my audience section 8, article I of the Constitution, the only reason we propounded the Federal Government was to raise armies and coin currency and punish piracy and things like that. There is no mention of toxicity or any of those kinds of things.

What I heard from each of you is that a key to the effective societal response to the problem of toxic substances is knowledge. Whether you look at it in terms of the individual member of our society or the institutions that operate in our society or those who are elected and make mountains between the two of them, a knowledge of what it is we are dealing with and how we are thus better to deal with it becomes extremely important.

My own sense of national purpose is, I tend to say, sort of ridiculous to devolve down to the lowest element of society the task of generating knowledge that is important to 233 million people in this case and in the case of toxic substances to people all over the world. I come on strong and say we have to reaffirm a national base of commitment to the development of knowledge.

There is always a prioritization process that is going on with what resources seem to be available. We have lived through at least 2 years of apparent abandonment of the search for knowledge, or at least the devolution of that search down to some other level of government or into the private sector. At the same time, it seems we have lived with a notion that perhaps we have been at this national environmental protection long enough so we can start devolving to State and local government more responsibility for dealing with some of these problems.

Perhaps as a starter, since each of you has dealt in a variety of ways with specific problems, I wonder if you wouldn't try to react briefly to how you have seen us organize ourselves as a society to deal with these kinds of problems, and if you can't see some improvements in the way we have, in effect, organized ourselves to deal with a lot of these problems, and I say that, keep it very general in your reaction looking at the role of the National Government, the role of State governments and the important role that our private institutions need to play, those who produce chemicals, those who in one way or another formulate, and whatever else we do with those chemicals, looking at it in sort of an institutional sense. Is there a better way for us as a nation to organize ourselves to deal with the environment? I invite any of you to be the first to comment. Dr. Cooper?

Dr. COOPER. I think there is a delicate balance between what the Federal Government maintains control over and what they pass on to the States and what they can expect the private sector to voluntarily do.

During the last few years when we attempted to decentralize, the biggest laugh was monitoring the environment. That is a function the Federal Government really has and the capabilities and the budget and manpower to do. Most States are not capable of going out and doing the chemistry of air, water, food, et cetera.

The second basic thing I think the Federal Government must maintain is an aggressive attitude toward wanting the data. If the Government backs off on their enforcement, industries are going to back off on spending any money on basic R&D for environmental risk assessment. We saw it in the last 2 years. They do it because the regulations are there and they have to protect themselves. The States are not in any position to do that.

The third thing, if you want to decentralize to the State government, is the whole problem of interstate commerce and one State taking an aggressive role in the environment and the next State wanting jobs instead, and you have the cost unbelievable competition taking place with different perceived tradeoffs.

Where the States have a real role to play, they are much more capable of making rapid decisions relevant to the local populations. They are close at hand and know the problems and can move fast.

Senator DURENBERGER. Do any of the other witnesses want to comment?

Dr. FINKLEA. Yes. I certainly think the National Government has a very strong role to play in terms of research and certainly in supporting things like curriculum development that could be used across the country. I, too, would support national regulations which give some uniformity, but the States have a very important regulatory role to play, too.

I think now that the States are probably not the knowledge reservoir they should be. I think once the National Government generates the information, it should be accessible to States and to local governments. There are some double things in the field I work with that would be helpful. For example, one could distributed a Federal paperback book on the recognition of the diseases related to chemical and other exposures to every hospital library. The Government has several thousand of these in its warehouses and the book is rapidly getting out of date. You might as well get it out to the community hospitals. Things of that sort would be helpful.

I think the State should provide consultation services in toxic substances problems, especially for small businesses, as they do now under the Occupational Safety and Health Act.

I think the States have shown they can provide information and education through their A&M type universities and agricultural extension services. We should somehow get the knowledge and education pushed out through State mechanisms. That would really be helpful.

State mechanisms should also be responsible for training of the people who are needed in this field. I think the Federal Government might play a supportive role, but it would be better if we can find a way to finance these at the State level.

Private institutions have a much larger role to play. What we really need is a concensus of what we are going to do. The national purpose is a very pertinent one. We spend too much of our resources fighting each other. There are a limited number of people knowledgeable about these problems, and they all spend too much of their time in public hearings talking about what they should do and then they are not going out doing it. We need a better concensus.

Certainly private institutions can do the best jobs in control technology development. The Government may have some role to play here, but industry can develop the techniques that are needed. Certainly maybe the Government needs to work with industry so you can try out various forms of control technology before you move into full-scale regulations. One of the problems I have noticed as a physician is that sometimes our Federal regulations get in place and have not been well tried. For example, the occupational safety and health field, we have a regulation dealing—a whole series of provisions—dealing with the emissions in coke ovens. Unfortunately, the productivity of coke ovens has fallen partially as a result of those regulations. The specific aspect I want to address is the medical aspect. We included in the regulations some procedures that turned out not very helpful but are very costly. The best health result, from my point of view, we got from the coke oven medical program is we have controlled hypertension among the coke oven workers. You should see these fellows; 30 percent of them are hypertensive. The fact that we are there once or twice a year reminds people, "Hey, you ought to see your doctor and take your medication." That is all it takes.

I think the private institutions can do a lot in control technology development and, also, in evaluating what you might do in terms of regulation before they are promulgated by the Federal Government. Private institutions can also help assess or evaluate regulations. We tend to put things into effect and then not see what kind of a job they are doing. I am pleased to see you are conducting these oversight hearings. There is a lot more mileage sometimes in new laws rather than the hard job of oversight and the evaluating how effective regulations are.

Those are some of the institutional things I think might be helpful.

Senator **Durenberger**. I take it you had considerable experience with OSHA? It strikes me the safety part of OSHA is the easy part, and the part that can be more easily devolved at this state of the game. The health part is the one that is so very, very difficult and a lot of problems in the workplace.

Dr. **Finklea**. Certainly I think the industry has done a good job when it organized itself, especially in preventing accidents, especially lost time accidents. Accidental injury remains a problem, but it is a little easier to deal with, both in terms of prevention and compensation, than are the occupational health problems that may be related etiologically to work place exposures or aggravated by exposures to dust and chemicals.

Senator **Durenberger**. Dr. Kneip.

Dr. **Kneip**. Senator, I think there are those in the audience who might suggest the reading of the Constitution clause about piracy covers toxic materials.

A couple of comments on something you brought up. I have watched the research funding available for the foundations funded by industry, industrial funds, State funds all decreasing at the same time the Federal funds are decreasing. The climate of research funding in the environmental area has been severe to the point that a number of young scientists have had their careers terminated or are living under the constant threat that within a year or so they may not have funding anymore. It is really a rather severe situation.

In the area of devolving, when the OSHA Act was written, there was a clause that encouraged States to initiate occupational hygiene in departments within the State with, I believe, 50 percent Federal funding, on the premise that the Federal funds would eventually terminate. I believe several States did initiate and carry on that work.

In the case of New York and New Jersey, existing occupational hygiene programs were terminated when the Federal funding terminated. The States accepted the initial 50-percent support for the existing programs, but when the Federal funding stopped, they turned over all the occupational work to the Federal people and closed the State departments. The idea of turning things over to the States may depend very strongly on the State's financial ability to support the work.

Senator **Durenberger**. I have been reminded of several things to ask the industry people on Monday. One I won't ask you to respond to, but Dr. Cooper mentioned the whole issue of accountability and how we can improve the system of accountability.

One other general question before I excuse this panel, is the issue of—again, it relates to problems of limited resources and how we are going to go about this in a way in which we can make the greatest utilization of knowledge—that is the question as to your observation about public concern or the toxicity that you find in your daily lives, and we read about the degree of tolerance that we can expect from the public in America as we try to find our way to some better solution for this problem.

Dr. Cooper, you said Michigan obviously had a lot of experience over the last 10 years. Each of you in a way have had personal experiences in this area. Can we expect the public in this country to be tolerant of a deliberate knowledge base approach that might not get us to perfect solutions of all these problems?

Dr. **Cooper**. It is kind of interesting, in the last couple years—of course, I am from a State who was No. 1 in terms of unemployment—there was no indication of any rollback on environmental quality. People say something is going to give, we can't have jobs and clean environment at the same time, the whole works. It didn't happen. Coming from a State also where we have frequent enough episodes on "60 Minutes" to keep a nice, healthy social level of hysteria, one does not have to go out and generate enthusiasm about the environment.

You will find a lot of difference in attitude from State to State depending whether or not they are experienced in kepone and

PCB. They are aggressive because of the rate of public demand. I think the tendency is for people to be somewhat apathetic until it gets in their backyard and then they are madder than hell. You will get different responses. One is a generic response, which is a national problem. You will get a much more hysterical response if it is closer to their own backyard.

Senator **Durenberger**. In New York, do the New Yorkers care about anything other than the Giants, the Jets, the Islanders?

Dr. **Kneip**. Certainly. The Love Canal received a great deal of attention. I think that is an example of one of the major problems. The problem of defining the toxicity in a particular situation or the interspecies extrapolation, the fact dioxin is extremely toxic to some species, not so toxic to others, and we don't know how toxic to humans.

If you mention dioxin, there is a great deal of concern because it is known as the most toxic material there is. I think the only way we will ever get any tolerance is when we have a better data base, a better knowledge behind all of this.

Interspecies extrapolation, the problems of bioassay results of the mixtures of materials, or the possibility of synergism, whatever, are really rather unknown. We are always faced with this in environmental problems. As long as the hazard is in your backyard, as Dr. Cooper said, there will be a great deal of concern.

Senator **Durenberger**. Dr. Finklea.

Dr. **Finklea**. I am promd of two accomplishments that occurred in the last decade. First is a lot of our lakes and rivers which didn't used to have fish have fish now. The second is that Birmingham used to be one of the more polluted cities in the United States, and it is a very clean city now. Unfortunately, in the last few months, it has been clean in part because our steel industry has been closed down. We would like to see that opened back up. Maybe things would not be so pristine, but we would have a few more jobs.

In terms of the chemical problems, I think the people in our State are most concerned about improper disposal of toxic waste. We have a very good disposal facility which is, in general, well run in the southern part of our State. There have been some problems with other people alledgedly disposing hazardous materials or wanting to dispose of them in the old strip mines or abandoned underground mines creating aquifer problems, as Dr. Cooper has referred to.

I guess on a personal basis, people are concerned about getting access to information. How do I get this? About personal exposure to chemicals information is a frequent question. We get a lot of questions of this type from our colleagues over at the Center of Labor Education and Research. This is a continuing, very difficult problem for people who are working and sometimes for people who are buying materials. The labeling of industrial and commercial chemicals is just not very good, and the material safety data sheets are not what we would like.

Senator **Durenberger**. I understand if somebody finds something in a well in a little suburban community then that is a big problem. How about the workplace, or how about just as people use their glue, their paint, whatever they do, I take it there isn't the same kind of concern. Dr. Kneip talked about the problem of reproduction. Are people in the workplace all upset with the kind of chemicals they deal with today or are we really only in the public concern stage? Are we really only at the stage they are concerned about things like groundwater contamination?

Dr. **Finklea**. I think it depends on the depth of knowledge of the employer group and employee group. You have certain groups where the problem is well understood and discussed, like the insulation workers. Of course, there are very, very severe health problems among these workers and their families. It is not just the work exposure but the material they take home that their children are exposed to. And it is a problem that is not going to be worked out very quickly. It is both a health risk and an occupational stress problem they just have to live with.

Among other groups and industries where you have established mechanisms, as in steelmaking, I think it is more how do you make the system work in their industry. Small business people have a lot of concern about chemical hazards but it is generally on an individual basis and usually when a specific problem comes up. Someone will get sick or one or two people will develop a malignancy. Oftentimes we don't have any answer for those problems and most times they are probably not related. Basically, people are really concerned about the right to know what they are working with.

Dr. **Kneip**. I am the chairman of our safety committee in the Institute. There is a concern particularly when a woman gets pregnant. They get quite concerned about what they are working with. We tried to face this. The Institute does a lot of work with toxic materials and carcinogens. We have made efforts to transfer people from one job to another if we think there is any possibility of some slight chance of an exposure. The medical center itself is trying to formulate a policy with relation to that. There is definitely concern all over. It is a big mystery. It is one of the things that is most difficult to deal with.

Senator **Durenberger**. Thank you all very much. As I indicated, I will be sending you a series of questions which will appear with your answers in the record. Thank you, gentlemen.

Our next witness is Mr. Donald Clay, Acting Assistant Administrator, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Don, I welcome you. I understand you had an accident on the way to work. I noticed you smiling when one of the witnesses said something about we spend too much time in hearing and not enough doing.

I always remember my first year here when we had an energy crisis and the Secretary of Energy figured out he spent about 95 percent of his time at things like this and the rest of his time trying to deal with the energy crisis.

We welcome you here. I say to those who don't know, Don is a marathoner and broke his arm running. I have always advised people not to jog. I was always quick with the Mayo Clinic study of how it ruined your knees. Now I have a broken arm as further testimony. We welcome you here and look forward to your testimony.

STATEMENT OF DONALD CLAY, ACTING ASSISTANT ADMINISTRATOR, OFFICE OF PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY MARCIA WILLIAMS, ACTING DIRECTOR, OFFICE OF TOXIC SUBSTANCES, AND ED JOHNSON, DIRECTOR, OFFICE OF PESTICIDES PROGRAM

Mr. CLAY. Thank you very much, Mr. Chairman. I am pleased to be here this morning to have the opportunity to testify before you today.

Senator DURENBERGER. Don, before you get started, will you introduce the people with you?

Mr. CLAY. On my left is Marcia Williams who is the Acting Director of Office of Toxic Substances and Ed Johnson is Director of the Office of Pesticides Program. I am here as the Acting Assistant Administrator of Pesticides and Toxic Substances.

As you are aware, this is a time of transition in EPA. Administrator Ruckelshaus is in the process of installing his senior management team. Over the next few months, I am sure he will be addressing a variety of policy and legislative issues including those dealing with toxic substances. I hope my remarks today can help set the stage for what I believe will be a renewed EPA emphasis on a strong innovative toxic substances program for the future.

With your permission, Mr. Chairman, I would like to submit my written testimony for the record.

Senator DURENBERGER. It will be made a part of the record.

Mr. CLAY. The Office of Pesticides and Toxic Substances regulates toxic substances primarily under two laws: The Federal Insecticide, Fungicide and Rodenticide Act, or FIFRA, and the Toxic Substances Control Act, or TSCA. Together, these laws allow EPA to evaluate and, if necessary, to control the way chemicals can be used in order to protect human health or the environment.

Under these laws, EPA has authority to collect information about chemicals, such as how much is produced and where; how many people are exposed; what is known about the chemical's toxicity; and environmental effects and how the chemical is being used. If necessary, based on this information, EPA can safeguard public health or the environment by controlling the chemical at the most appropriate stage, whether that involves banning it completely, controlling initial manufacture, putting conditions on use and disposal practices or anything in between.

FIFRA and TSCA have more in common, however, than their authorities to gather information, evaluate and control. Both were initially written by Congress as risk-benefit statutes. This balancing of risks and benefits underlies the regulatory decisions of both laws. This means that when evaluating a chemical, whether as a pesticide or a chemical bound for other industrial use, EPA must determine whether that chemical can perform its intended function without causing unreasonable risks or unreasonable adverse effects.

The concept of unreasonableness reflects a judgment that the probability and magnitude of harm to society from the use of a chemical is likely to outweigh the benefits.

I would like, at this point to turn to the description of program goals and accomplishments. At the committee's request, I am emphasizing TSCA. Congress enacted TSCA in recognition of what it perceived to be loopholes among existing statutes that were limited in scope to a specific environmental problem. In TSCA, Congress gave EPA general authority to regulate manufacture, distribution, and use of harmful chemicals, both those that are already in commercial use and those that have yet to be manufactured. Action should be taken only when public health and the environment suffer, were the action not taken.

EPA was given sweeping authority to collect both scientific and economic data about chemicals. These data, Congress hoped, would begin to build a centralized base of information to support sensible and effective chemical regulations.

While these authorities are impressive, Congress did not intend they be used in a vacuum. TSCA is definitely a risk-balancing statute. Section 2 of TSCA requires EPA to carefully consider the impacts of its decisions and to assure that they do not create unnecessary burdens to technical innovation. Further, this section of the law states Congress intends that EPA consider three primary impacts of any action: the environmental, economic, and societal.

In addition to the risk-balancing aspect of the statute, there is another unique feature of TSCA. Since TSCA authorities are specific and used to address a chemical wherever it is found, the potential for TSCA action duplicating the action of other EPA offices or other Federal agencies is high. Thus, Congress directed EPA to coordinate with other Federal programs, to share information and risk determinations and to defer action to other laws where authority to take action exists elsewhere.

Our actions to date have resulted in a variety of programs, but I am also committed to doing more in this area. I do not use TSCA referral mechanisms as an opportunity to avoid action, but rather an opportunity for coordination.

Turning now to the implementation of the law, I would like to put the program's current and future activities into historical perspective. When I became Director of the Office of Toxic Substances in 1981, proposed regulations and policies were at a baseline level for the TSCA program. I established TSCA's first operating priorities. These priorities were printed in January 1982 in a report we call the "100 Day Report." As a result of that effort, we were able to focus our efforts to use most of the provisions of the law and to think creatively about ways to integrate various TSCA authorities. After 2 years experience, we have updated the report. This second report on TSCA priorities and progress was just issued this month, and the subcommittee has received copies.

Now I would like to turn the discussion to the three major authorities inherent in TSCA. These are data collection, review and evaluation of new chemical substances and reduction of exposure to existing chemicals.

TSCA contains authority for gathering two basic types of information: chemical production and use information and data from health and environmental effects testing. Section 8 of TSCA includes several reporting requirements for production and use information. It requires EPA to establish an updated list containing every chemical known to be in production or imported into the United States.

The chemical inventory was first published in 1979 and new chemicals have been added and includes basic information on nearly 60,000 existing chemicals.

Other subsections in TSCA's section 8 allow EPA to require companies to submit scientific data or reports of adverse health effects which otherwise would be unavailable to EPA. For example, a final rule was published in September 1982 requiring manufacturers to submit unpublished health and safety studies on specific chemicals. As a result, approximately 4,300 unpublished health and safety studies were submitted. Another subsection of section 8 requires manufacturers to notify EPA when they receive information that any chemical may present a significant risk to health or the environment. Substantial risk notices are being received at the rate of approximately 70 per year.

Chemical testing is the second major source of data for EPA and authority to require such testing is contained in section 4 of TSCA. No other regulatory agency can require manufacturers to test industrial chemicals for a full range of human health or environmental effects.

To require testing, EPA must first find that the chemical either may present an unreasonable risk or is or will be produced in quantities which may result in substantial environmental release or human exposure.

Second, EPA must find that data are insufficient to evaluate the chemical and that testing is necessary to develop data concerning potential adverse effects.

When I arrived at the agency in 1981, EPA was under court order because of its backlog of testing decisions for specific chemicals. The court schedule called for elimination of the backlog by January 1984. In addition to my commitment to meeting these deadlines, I emphasized the importance of developing needed test data rapidly so potential risk can be identified as soon as possible. As a result, in certain cases, we are negotiating testing programs with manufacturers or industrial consortia, if this will result in receipt of needed test data substantially sooner than would be the case if we proposed test rules.

I would like to emphasize that while we see negotiated testing agreements as an effective way to speed receipt of test data, we do not believe that all chemicals are appropriate for negotiation.

One final note on testing as it applies to data collection. By January 1984, the ITC backlog will be eliminated. We will then be able to use other internal mechanisms to identify added chemicals for testing.

I would like to turn now to the third major authority under TSCA, review and evaluation of new chemical substances. As I am sure you know, TSCA's section 5 gives EPA authority to review all new chemicals before they are manufactured. This provision is called premanufacture or PMN review, and by law, EPA has 90 days to review a new chemical. If EPA takes no action, the manufacturer is free to commercialize the chemical. However, EPA can restrict or stop commercialization entirely if there are concerns about a chemical's health or environmental effect.

In reviewing a new chemical, EPA assesses the exposure to the chemical throughout the chemical life cycle. This includes an assessment of potential human exposure in the industrial, commercial and consumer settings, and an analysis of potential releases to streams and persistence in soils and sediments. In almost four years of new chemical review, EPA has gained valuable experience that has led to a more effective review of new chemicals. More new chemicals than ever are going into detailed review. More conditions are being put on the use of chemicals and the exposure of workers during manufacture.

One final example of future action in the new chemical program concerns the area of biotechnology. Biotechnology has been until very recently a laboratory-scale phenomenon. However, commercial uses potentially subject to TSCA regulation are now under development. Significant risks may be associated with some of these uses of biotechnical substances, particularly as a result of their release into the environment. We are reviewing the applicability of TSCA to these products and considering the possibility of broader efforts to reduce environmental risk.

Thus far, we have been discussing the process for EPA's review of a new chemical. In addition to refining that process, we have a relatively new complement to the PMN review that protects public health and environment and potential adverse effects of new chemicals. The new program monitors chemicals which complete the PMN review but about which EPA may have fur- ther concerns should their use or exposure change. We call this our follow-up program. We take follow-up actions if we are concerned about a chemical's toxicity and have identified possible changes in exposure which can lead to increased risk.

One of the major objectives in the TSCA program during the last 2 years is to get the existing chemical program off the ground. Recognizing this problem last fall, I set up an existing chemical task force within the Office of Toxic Substances. I decided that rather than try to rank all existing chemical substances, I would begin action on those we knew needed controls because of information already available. The existing chemical task operates according to a set of priorities. Attention is focused on existing chemicals, one, for which section 4 test data has been received; two, on which substantial risk notices have been filed; third, on whether test data have been received from such sources as the National Toxicology Program or citizen petitions; and fourth, for chemicals or categories of chemicals which consistently raise concerns during PMN review and which are similar to categories of existing chemicals.

The task force to date has conducted reviews of 60 substances identified through the mechanisms above. About two-thirds are targeted for further analysis, and five have already moved into regulatory development.

We have also initiated our first action under section 4(f) of TSCA. Section 4(f) contains a process for priority accelerated review of chemicals suspected of causing serious or widespread harm to health or the environment.

Another important area, asbestos, has been the subject of OTS activities since the early years of the program. Recently, however, OTS has taken important steps for consolidating efforts toward asbestos and insuring a coordinated approach by the various regulatory authorities concerned with this material. Representatives of OSHA and CPSC are members of this task force, and other agencies will be invited to join as the task force moves along.

In this regard, OSHA is working to strengthen its workplace standards for asbestos. Complementary to this activity, we plan to publish a proposed rule in the next year banning certain asbestos product categories, and we plan to issue either an ANPR or a proposal which would establish a staged production cap on remaining asbestos uses.

My staff is also pushing ahead this summer with a survey of asbestos in public buildings to assist us in determining the nature and extent of any problem with friable asbestos material in such places.

Mr. Chairman, I believe we should continue to do a job of getting public participation in our TSCA decisions and publicly stating our rationales for making decisions. We have started putting our primary chemical assessment document out for public comment, and we now publish quarterly reports for both new and existing chemical decisions. Partnerships with States and the EPA regions are particularly important as we move toward sharing data which is now coming in.

In summary, I feel confident with the course I have set: to collect enough information to identify and categorize problems, coordinate with other EPA programs and other Federal agencies to encourage action under appropriate authority; and when there is a void to fill it with action under TSCA. Thank you for your attention.

Senator DURENBERGER. In the area of testing existing chemicals under section 4, there is a part of your progress report which says that results from around 450 negotiated toxicity studies will be received during the next 18 months and goes on to say, "A higher proportion of ITC chemicals will be subject to test rules rather than negotiated testing," and that "These chemicals tend to present more complicated issues."

At the same time, you talk about a steady increase in risk assessment and regulatory activity concerning existing chemicals. My question will be the reality of your goals and the means of accomplishing those goals. Could you, for the sake of telling us how you are going to achieve those goals, describe the trends at EPA of scientific personnel and resources over the last 3 years and what you expect in the next 2 years, what kind of skill mix do you have assigned to this?

Mr. CLAY. Certainly I can describe the trends in the past 2 years better than I can forecast the next several years. We do have somewhat of a skill imbalance problem in the FIFRA area perhaps more so than TSCA. We have requested resources. Congress has seen fit to provide supplemental resources, and we certainly have discussed with the new Administrator our desire to have some of those new resources. We have enough resources on hand to do what is statutorily mandated. However, there are many things under both acts that we believe need to be done, and we can certainly use more resources to do that. Is that enough or not?

Senator DURENBERGER. It depends on what that note says.

Mr. **Clay**. Let's read it here together. It points out that the scientific staff has been more stable than the rest of the organization. While we have lost a number of people, particularly out of the Office of Toxic Substances, we lost scientists at a lower rate than we have other people. There are 100 some less people in the Office of Toxic Substances than when I came in the door 2 years ago. Some of those have been scientists, but it hasn't been the biggest turnover area.

Senator **Durenberger**. I am curious and maybe I shouldn't get too far into the issue since you are not all too sure about the next 2 years, but let's deal with the present. Talk to me a little bit about present workload. Are they sticking around because they only have 6 hours a day?

Mr. **Clay**. No. One of the things I checked into recently was to find how much people were working overtime. Between FIFRA and TSCA we had over 400 people working voluntarily during the past six weekends. We had people signing into Toxics over the Fourth of July in an unair-conditioned building. We have a very dedicated staff of people. The amount of people we have at all levels, particularly the scientific level and program management level, work very hard. We have achieved a lot of what we have achieved, I think, at the expense of these people. They are tired and they won't work forever, but they are working awfully hard now.

Senator **Durenberger**. I read an article in the New York Times last Sunday about some of the abuses in EPA and a story about how the President of the United States gave a quiz about whether it was manure or the pony. I don't know if he ever gave you the quiz.

Mr. **Clay**. No.

Senator **Durenberger**. It sounds like all these scientists have found the pony rather than the manure. You can't expect that to last very long.

You can't speak for the Administrator, but does he expect these people to work in unair-conditioned buildings for the umpteenth weekend?

Mr. **Clay**. He has a real concern about the people at EPA.

Senator **Durenberger**. Is it likely, given the fact you have some stability in the scientific area, given all the things we know about the need for the greater application of that scientific knowledge that with supplemental funds available and with some refortification of the budget it is likely this area is going to be getting substantially more attention in a financial sense?

Mr. **Clay**. We certainly give it all the attention for resources we can get for it. Much of the work of the program is beyond our control. We can't control the number of registrations, et cetera. What tends to happen in times of scarce resources, in the TSCA case, in existing chemicals, we have taken cuts. During congressional oversight they ask us, "Why haven't you done more?" Evaluation of existing chemicals isn't nearly as driving as the PMN's coming in the door with a statutory deadline for review or the statutory deadline for testing decisions.

Senator **Durenberger**. Section 14 of TSCA provides that EPA may not disclose confidential business information to the public. I wonder if you would describe your interpretation of confidential business information, describe how EPA reviews claims of confidentiality to determine whether it is legitimate business or trade secret, how many items of information come in each month marked "confidential" of the percentage of the total? A recent AP submission on a substance that causes bone cancer in rats, in that case both the name of the chemical and name of the company claimed to be confidential. Do you allow that claim and what is the rationale of keeping secret the name of a chemical that may cause bone cancer?

Mr. CLAY. Talking in general terms, much of the information we get is claimed confidential. In terms of PMN submissions we get at the rate of 100 a month now, something in excess of 90 percent have some portion claimed confidential. We do not routinely challenge the confidential claims of the manufacturer who makes one. In the early days of the program, we did. We had a program of CBI substantiation. We had a whole procedure of going back and requesting more information, and then the EPA rules required the General Counsel to make a determination.

What we were finding was that the company was prevailing in all cases. Given the statutory definition of what was confidential, the General Counsel's Office at EPA was upholding the confidentiality claims. As a result, we don't routinely challenge CBI claims any more.

In reference to the bone cancer, that would not have been challenged. If somebody were to ask for that under a Freedom of Information request, we would, in fact, go back and substantiate that was a valid confidential claim. We do have procedures for doing that. The ultimate authority for deciding that within EPA is the General Counsel's Office.

Ms. WILLIAMS. The number that review it is probably on the order of, I would say, 10, but that is a rough estimate. They are reviewing it for the purpose of making sure CBI is properly marked and taken care of.

On the PMN's, there is virtually 80, 90 percent have at least one of the items claimed confidential. There is a sanitized version of all the new chemical actions put into the public file as well as sanitized versions of any other kind of incoming information put into the public file for access.

I might also comment that most of the 8(e) submissions or the substantial risk notices we receive do not have the same high percentage of CBI marked that the incoming PMN's do.

Senator DURENBERGER. Are you confident, with the present definition the counsels of EPA are operating under with regard to confidentiality that it is appropriate and doesn't interfere with your work in any way?

Mr. CLAY. It certainly interferes with the conflict of trying to share information with other people and trying to involve the public in the decision process. For example, we can't share confidential information with States. It is a very complex subject because companies have rights to the information, too. We are working this problem in both programs and developing ways of trying to share more information. You bounce off the public's right to know what we are doing and review our decisions versus the company's right to generate data and have that kept as proprietary secrets.

Senator DURENBERGER. I can see in the beginning where it would be a confidence-building measure. If you wanted compliance with requirements of the act and there isn't assurance to businesses and most of the chemical businesses are very competitive, that there is a value in confidence-building nature in being able to label something confidential, I would be curious to know at some point some trust relationship builds up here, there aren't some trust advantages to changing that definition.

Mr. CLAY. I think your industrial witnesses will be testifying the other way of the need to make the description more tight than we have now.

Senator DURENBERGER. Is the same situation true with regard to pesticides?

Mr. CLAY. Somewhat, I think. Ed might speak to it. There seems to be the same proprietary rights to the data.

Mr. JOHNSON. This is an issue that has been addressed several times by the Congress as to how to better define kinds of information that ought to be made publicly available and those data that should be considered to be confidential business information. Certainly the House Committee on Justice in the 1978 amendments tried to specify the kinds of information that could be released. We have been challenged on the release of some of this information under definitions in court cases.

It seems to be evolving into the situation where industry is not so much concerned about keeping it secret but protecting its use in economic situations. That is, they are not concerned with telling the public what the results of the studies are and, indeed, provide some limited access to those studies in the way people can't carry off the information.

But they are concerned about information and studies particularly being carried overseas and being used to their economic disadvantage. It is a very tricky issue and requires a lot of balancing. I think it is a bit more than the toxic people have so far. I can't say we have reached a final conclusion to it because it seems to be evolving into something that might prove to be workable.

Mr. CLAY. Mr. Ruckelshaus is interested in and charged with over the next year in finding more innovative and creative ways of sharing this information.

Senator DURENBERGER. The recent commerce report states the OTS projected several general analyses of chemicals. The report measures azo dyes and ZDDP's. Are there other examples you could add to that? Are there similar recurrent problem areas defined by factors other than chemical family, for example, exposure scenarios? I understand you reviewed something in the neighborhood of 3,000 PMN's. Do you now know enough to identify some problem categories of chemicals and those that always or usually raise concerns about risk?

Mr. CLAY. Yes; that is one of the areas we pointed out in the report that we are emphasizing. Now that we have reviewed over 2,600 PMN's there are some categories where we believe other than the statutorily mandated data would be very useful in the analysis. We are looking at several mechanisms for getting that data.

One mechanism we are exploring is the use of a circular saying that in this category of chemical we would generally expect to see a particular type of data. Then if the PMN came in and didn't have that type of data, we would have to be convinced either that we didn't need it or we would require the data. An alternative way of doing that would be to issue a section 4 rule, and we do hope to be choosing some of our own section 4 testing rules on existing chemicals, but that also triggers requirements for PMNS of the same family to have testing data associated with them.

And the third alternative is the use of the risk list which is 5(b)(4), to make that kind of finding would require the summation of data. One of the trends you will see in the program now that we do have experience, is that we can now better identify chemicals or categories where we would like to see certain types of data.

There is some reason to believe that industry would not be opposed to this new trend. In many cases, the excuse we hear is, "Why didn't you ask, for any data." "We didn't know what you wanted done." There are many ways to form the testing request so that there is guidance ahead of time.

Senator **Durenberger**. Your recent progress report says you are exploring the possibility of using TSCA's section 8(a) information data to support other agencies and other EPA offices. My question is why is that statement phrased in a somewhat tentative fashion? Can you give us examples of how that might be used?

Mr. **Clay**. Even more so is what I meant to say. The section 8 asbestos rule, for example, was worked out with both CPSC and OSHA. We are receiving and sharing that data. What is meant in the progress report is that the purpose of TSCA was to gather information for others to use. The production of information for others is a useful end point in and of itself in TSCA. It is meant to do that. We haven't done that as much as we would like. That is one of the things we would like to move into.

Ms. **Williams**. I was going to give you a couple examples on the previous question. There are other categories besides the ones mentioned. Some of those are based on structure and some are based on the new situations since exposure is what is the driving force.

Just to throw out two more to you, one would be the flame retardant area. Another would be the area of reprocessed solvents that we are looking at more as a class.

The other comment I would like to make, again, going back, on the class concept, we think it is a useful concept to proceed with not only for the new chemical reviews, but also existing chemical reviews. Quite often if you are dealing with a use category, you go chemical by chemical, you could be getting into a situation where you solve a problem for one chemical and have a range of substitutes out there that is really just as big a problem. We are taking a look at these use clusters so we can come up with some kind of a fix and one of the witnesses said, we might actually take time to fix the full extent of the problem and not just one particular chemical problem.

In terms of the use of TSCA to share other kinds of information, I think there are a number of areas where TSCA can be useful. 8(a) is certainly one area where we can go out and get production information. Probably Superfund is one part of EPA that will find some of the information we have the ability to obtain extremely useful.

Clearly, the idea of using section 4 to obtain test data would be useful to other agencies in other parts of EPA as well as OTS. There have been preliminary discussions with both the Water Office and Air Office in the hazardous pollution area. They might be able to use TSCA section 4 to get some useful information.

Also, there have been discussions about the concept of using TSCA in the control area to better obtain fixes on certain problems that other parts of the agency have. Again, we had discussions with the Water Office in the case of the possibility of using section 6 to get quality control information. The whole range of TSCA authority can probably be extremely useful to other agencies in other parts of EPA as well as OTS.

Senator DURENBERGER. I wonder if you can give me a date when the new chemical categories concerned will be defined? I am told by staff who preceded me in this oversight function that we have been waiting since about 1979 for these categories. Can you make a promise here on record, give us some date?

Mr. CLAY. Let me consult for a second.

We will have the categories defined by this fall. The actual promulgation depends on the results of discussions with the Administrator on resources, what have you. It is clearly one of the discretionary areas.

Senator DURENBERGER. This may be the last question. I am curious what steps OTS has taken that 8(e) notices are seen by other companies who handle those chemicals? Does the current research and dissemination of confidential information in any way inhibit the exchange of risk level information?

Mr. CLAY. As Ms. Williams said earlier, most of the 8(e)'s I have seen have not been CBI. Very few are CBI information.

Senator DURENBERGER. Most of it is being shared then or can be?

Mr. CLAY. Can be, has been.

Ms. WILLIAMS. Is routinely, as a matter of fact. We routinely send notices to quite a few other agencies—OSHA, CPSC—and we also share them with other parts of EPA. In fact, one example of that, when we received the study in from API on the unleaded gasoline, that came in to us through an 8(e) submission. We are the ones who shared it with the Office of Air Programs in EPA.

Senator DURENBERGER. I asked about companies who are handling comparable chemicals.

Ms. WILLIAMS. All the information we get under 8(e) is routinely shared with other Federal agencies as well as other parts of EPA.

Mr. CLAY. One of the things we would like to do more of are chemical advisories where we, in fact, come up with kinds of information which is certainly not worthy of regulatory action at this time but warrents some concern nevertheless. We might have heard about it from other places or the company might have shared what they are doing. Our intent is to get this information out to other companies so they can take similar actions.

Senator DURENBERGER. That is an intention or is already going on?

Mr. CLAY. That is planned, but we do it somewhat. We have one in review. We have more coming.

Senator DURENBERGER. How many more? Any idea?

Ms. WILLIAMS. We are currently working on two. That is an issue of you need to find the proper types of things that you think are appropriate for advisories as opposed to rulemaking of some kind. There is a fine line between things that you think are only worthy of advising versus things you think are appropriate to go forward into rulemaking. There are two being worked on now.

Senator DURENBERGER. Besides that fine line, what are the other restraints on sharing this kind of information with other companies?

Ms. WILLIAMS. Again, we have in 8(e) cases shared information—I misunderstood you. There have been cases where we got an 8(e) from a company and shared that information with other companies that are in a similar situation making a similar product. That also happens routinely. It is usually possible to do that without concern about CBI. You can mask a CBI. The 8(e) information is still being screened for CBI. We did get more CBI claims in on the 8(e) information than we expected to get in. We are working with the companies right now because we do fully expect to be able to share the information that came in under 8(e).

Senator DURENBERGER. That is going to have to be all the questions. I need to vote on the Paul Volcker nomination. I appreciate the testimony and responsiveness. If we have other questions, we will submit those to you. Thank you very much. The hearing is adjourned.

[Whereupon, at 11:55 a.m., the hearing was recessed, to reconvene Friday, July 29, 1983, at 9:30 a.m.]

[Statements submitted for the record follow:]

Statement of
Dr. John F. Finklea
Professor of Preventive Medicine
School of Medicine
University of Alabama in Birmingham

Before the

SUBCOMMITTEE ON TOXIC SUBSTANCES
AND ENVIRONMENTAL OVERSIGHT

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

UNITED STATES SENATE

July 27, 1983

I am Dr. John F. Finklea, Professor of Preventive Medicine in the School of Medicine and Professor of Environmental Health in the School of Public Health at the University of Alabama in Birmingham. The teaching programs of our Department involve medical students, graduate students and resident physicians. We also work in research, patient care, community service and continuing education. Prior to joining the University in 1978, I worked for ten years as a Federal research scientist and as a manager of research programs dealing with either environmental health or occupational safety and health. From 1969 through 1975, I worked with programs dealing with pesticides or air pollution, then, from April 1975 until January 1978, my Federal assignment was to serve as director of the National Institute of Occupational Safety and Health (NIOSH). I appreciate the invitation of the Subcommittee and am pleased to serve as a panel member during your oversight hearings dealing with the Toxic Substances Control Act. I am not testifying today as a representative of my university but rather as a private citizen whose testimony is based upon personal knowledge and experience.

In his invitation the Chairman requested that this panel address several issues including the following:

- Health and environment threats leading to the enactment of the Toxic Substances Control Act and other environmental statutes.
- The effectiveness of these Acts in abating those threats.

While I worked in environmental and occupational health research for most of the decade prior to the passage of the Toxic Substances Control Act, I was not often directly involved with the process which led to the enactment of that legislation. However, I do clearly recall several hopes which we had for the legislation. The first major problem which we hoped would be dealt with was the premarketing assessment of industrial and commercial chemicals to decide whether or not marketing would pose a substantial degree of risk for adverse effects on either the environment or public health. The second group of problems which we hoped would be covered related to the safe use of commercial and industrial substances, especially chemicals. This latter consideration could also be viewed as a way to take care of problems which weren't dealt with very well in other environmental laws or in health and safety legislation. At least one person referred informally to the later function as a "tidying up" of other legislation.

When thinking about the first group of problems, that is lack of premarketing toxicity testing and assessment, several specific examples came to mind:

- In the late 1960's a chemist friend of mine was demonstrating to me the techniques for measurement of residues of chlorinated hydrocarbon pesticides in human sera collected from groups of workers exposed to pesticides and in human sera from the general population. After we covered the sample preparation techniques then used, he pointed out the residue chromatography peaks associated with some of the commonly used pesticides. I asked what might be responsible for a number of other peaks noted in sera from the general population. It turned out that polychlorinated byphenyls (PCB's) were responsible for these peaks and that we had stumbled on one of the first bits of evidence that PCB residues in humans were widespread and might pose a health risk. Not too much was known about the persistence of PCB's in the environment or their long-term effects on health at that time. PCB's were viewed as exceedingly useful compounds that provided, among other things, a beneficial degree of fire protection in transformers housed on or in buildings rather than as a material whose continued use would cause wide dissemination through the environment, threats to wildlife and concern about public health. We all hope the that Toxic Substances Control Act could prevent a recurrence of this kind of problem.

- During the late 1960's and early 1970's we were also concerned about other environmental contamination and environmental health problems including use of products that contained releasable asbestos and the accumulation of cadmium from various sources in the renal cortex of man. The asbestos problem has since that time grown into a major public health and legal issue with which you are probably quite familiar. The cadmium problem hasn't received too much attention. Our concern about cadmium was primarily based upon the realization that autopsy studies in industrialized countries showed that there was widespread accumulation of cadmium in the renal cortex to a level not far below that which was associated with altered kidney function. Cadmium exposures involve food, cigarette smoke, some occupations and, to a lesser extent, pesticides, sewage sludge and drinking water. I am not sure that the Toxic Substances Control Act has helped us very much with either the asbestos or the cadmium problem.

The more diverse, second grouping of problems included the following:

- We didn't have a good system for sharing information dealing with pesticides among several Federal agencies responsible for health and safety research or regulation. Toxicity testing information submitted to the Environmental Protection Agency was treated as a "trade secret" and not shared with those responsible for the health of workers manufacturing the pesticide or formulating the final product. This has, I think, been worked out.

- There were occasionally allegations that industry destroyed records needed for health studies of the long-term effects of chemical exposures. Industry felt these allegations were unjustified, saying that old, inactive personnel and medical records were routinely destroyed after varying periods of time. It costs money to keep these records for several decades. I believe that the Toxic Substances Control Act and OSHA regulations have dealt pretty well with this problem.

- Another problem was Federal right of entry to conduct workplace studies and for study of personnel and health records of current and past employees. This matter is addressed by both the Toxic Substances Control Act and regulations promulgated under the Occupational Safety and Health Act. In general, it seems to me that Federal officials now have the degree of access which is required.

- A fourth problem was that we didn't have any early warning system for newly emerging health problems. It wasn't clear what were the ethical and legal responsibilities of health personnel working for the private sector. For example, problems arising during the manufacture of leptophos and concern about the carcinogenicity of vinyl chloride monomer were not revealed in a timely fashion. Others have alleged that there were similar disclosure delays with information involving adverse effects realted to asbestos and dibromochloropropane (DBCP). It was generally agreed that there was need for an effective early warning system. Reporting of newly observed adverse health effects as required by the Toxic Substances Control Act has in my opinion been quite helpful.

- A fifth problem was that industrial and commercial chemicals were often poorly labelled and that it was difficult to disentangle what chemicals might be present in a commercial formulation containing several trade name products of uncertain composition. Needless to say, the materials safety data sheets for these products, if they were available, were often not very helpful. Without basic information of this sort, it is pretty difficult for the small employer to protect himself and his employees. This labelling failure and the incomplete materials safety data sheets remain a major problem in educating employers and employees. I personally have always felt that workers had a "right to know" what they were exposed to and the extent of such exposures. It really boils down to a "how in the heck do you find out" problem which is still very much with us.

- A sixth problem was how to get a better assessment of the chronic effects of repeated short-term exposures or long-term exposure to chemicals already being marketed. A mechanism was set up whereby an interagency committee could recommend to the EPA Administrator what chemicals should be tested by industry. The committee has made a number of recommendations to which EPA eventually replied in the Federal Register. However, it doesn't seem to me that EPA required industry to do very much in this matter. The chemical industry itself organized a facility to conduct toxicologic testing of a number of the industrial chemicals used in large quantities throughout the industry. This may or may not have happened without the toxic substance legislation. At any rate, it doesn't seem to me that the Act has worked very effectively in this matter.

- A seventh problem of major concern was the effects on reproduction of commercial and industrial chemicals. We didn't and don't now have enough information on the effects of commercial and industrial chemicals on reproduction.

- An eighth problem was that we didn't really know very much about the health hazards of chemicals produced primarily for export (like kepone and leptophos) or chemicals imported into this country. I really don't know whether or not EPA has established a good system to deal with these problems. I do know that countries which import chemicals from the United States would like to have a reliable source of information other than information from companies who directly benefit from sales of these products.

There is another set of concerns never far from sight and very difficult to resolve. Basically these involve how do you prevent legislation and regulation from making presumptions that cannot be supported scientifically. Likewise, how do you develop regulations, especially those dealing with toxicologic testing, that do not tend to freeze us into the acceptance of less than adequate methodology when better test methods may become available in the near future. There are many others in government and industry more qualified than myself whom you might want to ask about these problems.

One additional topic that those still in government might not discuss candidly with you is the matter of adequate funding to implement environmental laws and legislation dealing with health and safety. It often seemed that the Legislative Branch of government passed legislation that could not be implemented with the resources which were made available to the Executive Branch. There may be many reasons for allowing such a mismatch to occur, but the tendency to do so undermines trust and faith in our Federal Government. Those responsible for implementing the legislation sometimes take a cynical view of the disparity between legislative requirements and the resources made available. Certainly this seems to have been a problem with the Toxic Substances Control Act.

Mr. Chairman, I sincerely hope these remarks may be of some assistance to you and the Subcommittee. I would be pleased to try to answer any questions which you and members of this Subcommittee might wish to ask.

Statement of

Professor Theodore J. Kneip
Institute of Environmental Medicine
New York University Medical Center

to the

Senate Subcommittee on
Toxic Substances and Environmental Oversight

Senator David Durenberger
Chairman

July 27, 1983

My name is Theodore J. Kneip and I am a Professor in the Department of Environmental Medicine of New York University Medical Center. I received my Ph.D. with a major in Analytical Chemistry at the University of Illinois in 1954. I have had almost 30 years of experience in the problems of trace analysis with early emphasis on toxic or harmful impurities in drugs, reagents and uranium compounds, and 15 years spent in studies of toxic materials in air and water.

Although there are still problems to be addressed, it is important to recognize that past efforts have resulted in significant improvements in both air and water quality. In examining apparent gaps in environmental controls, we should also recall the reasons for existing legislation and regulations. For instance, the efforts to improve water quality were originally aimed at untreated sewage inputs and we still have not fully controlled such discharges, let alone toxic materials in the discharges.

Our laboratory has considerable experience in studies of contaminated sediments of the Hudson River Estuary. I have carried out such research and I have served on two Governor's Commissions and several panels which reviewed problems related to such contamination. Two of those problems were the subject of very recent court decisions, namely the polychlorinated biphenyls (PCBs) in the Hudson River and the mercury in Berry's Creek in the New Jersey Meadowlands.

In this testimony I will address the general problem of contaminated sediments, a second point regarding weaknesses in our current techniques for detecting toxic organic substances, and finally note the strong need for full understanding of environmental cycles before taking corrective steps.

The PCBs in the Hudson, the mercury in Berry's Creek and the cadmium in Foundry Cove near Cold Spring, New York (1) have a strong relationship. All occurred because of unregulated or even permitted discharges of what seemed to be negligible amounts of toxic substances. No one had an awareness of the fact that these materials would be accumulated by the sediments of the aquatic systems. No doubt there are many such cases of contamination on streams and estuaries around the United States. To date the only proposed solutions are to leave the deposits in place, to cap the deposits with clean material or to remove the sediments by dredging and placement in an acceptable hazardous waste burial site. However, each of the three cases I have cited is unique and no single solution is suitable for all of them.

The PCBs contaminated the striped bass in the Hudson River and required closing of the fishery. The cadmium contaminated blue claw crabs and resulted in a health advisory suggesting a limited intake of crabs. The mercury has produced no warning. The latter is only because edible fish do not enter Berry's Creek as there is a serious lack of oxygen in the water. Improved sewage treatment could restore the oxygen and the biota, with the possibility of a very serious human health hazard. The hazards in the other cases are already controlled in part and time is available for careful consideration as to the need for removal and possible further consequences of disturbing the deposits. Dredging is not recommended without careful monitoring of the surrounding waters for potential spreading of the contamination. Foundry Cove has already been dredged, with no signigicant improvement in the environmental contamination, and PCBs in Hudson River fish have been decreasing without any removal activity.

Beyond these local problems we must be aware of the very serious contamination of sediments in many harbors along our sea coasts. The amount of toxic materials entering the New York Bight is dominated by the inputs from dredge spoils, not by the sewage sludge which has received so much publicity. The contaminants include a mix of metals, PCBs, pesticides, polynuclear aromatic hydrocarbons and most probably a host of other toxic chemical substances which we have not identified.

The most serious difficulty in the problem of contaminated harbor sediments lies in the difficulty of defining the sources of the toxic materials. Regulatory efforts have sharply reduced direct industrial discharges, but many of these have simply been diverted to sewage treatment plants. The result is contaminated sewage sludge or effluent or both. Sewage outfalls may now carry a very significant fraction of such toxic inputs assuring continued contamination of the sediments which collect in our harbors and which must be dredged. Dr. O'Connor of our laboratory has estimated that some 38% of the PCBs entering the Hudson River Estuary in the late 1970's came from sewage effluents not from the upstream deposits (2).

Unless we define and control the sources, we will continue to face the difficulties which plague the PCB, mercury and cadmium problems, namely:

How to dredge without spreading the contamination or simply failing to remove it?

Where to put the large quantities of contaminated dredge spoils?

We must enforce the existing regulations for control of industrial discharges to sewage treatment plants, and make serious efforts to determine the sources and possibilities for control of the remaining materials which contaminate our harbor sediments. The Senate Subcommittee should institute a review of those cases of harbor sediment contamination which have already been investigated, and seek to define the extent to which the problems and general relationships have been defined. The findings should provide guidance for future reduction of the contamination through enforcement of existing regulations as well as for the possible need for new legislation.

Perhaps a more universal, but poorly recognized problem lies in the methods in use for analysis of toxic substances. The gas chromatographic technique coupled with a mass spectrometer (GC/MS) or other detectors can measure and identify extremely small quantities of toxic organic compounds. However, substances of low volatility will never reach the detector. Alternate methods which depend on high performance liquid chromatography are limited by the available detectors. Many of us are well aware that mutagenic and carcinogenic responses can be obtained by bioassay techniques on extract from environmental samples. The substances causing the responses rarely have been identified. Such knowledge has existed for many years, but has been neglected in the process of concentrating available resources on known problems or applications of existing methodology.

My laboratory has reported the apparent presence of unidentified non-volatile N-nitroso compounds in urban particulate matter samples (3) and a recent paper has reported significant concentrations of trichloro-acetic acid in water. Trichloroacetic acid is also a non-volatile material missed by the GC/MS technique. There is a need for a review of the available data on the existence of biologically active materials of a more polar and less volatile nature. The review should focus on the likely impacts of such materials and help to establish the need for research on new analytical screening methods needed to provide the data necessary to a better understanding of such problems.

Finally, we have learned our lessons regarding overall environmental interactions, and we must maintain a constant awareness of this most important fact. The possible impact of a toxic material may be modified, but not eliminated, by shifting it from place to place or from air to water to land. We cannot afford simple solutions which ban any specific discharge or placement of a toxic substance without full consideration of the alternate solutions. Often the earliest possible control in an industrial process, with a maximum recycle is the route of least impact. Containment as concentrated wastes in carefully controlled waste depositories is a secondary solution. Discharge to the environment has produced, and still produces, accumulations of contamination requiring further difficult decisions for their solution. Moreover, easy solutions to existing environmental contamination often are simple transfers from one discharge medium to another, i.e., from water to air or air to land. These easy answers may carry greater impacts or require more costly long term controls than more carefully thought out solutions undertaken at a more deliberate pace.

I believe current programs are beginning to emphasize so called multimedia considerations. However, it is important that this become part of the process at this point in time during the considerations which may lead to new legislation.

References

1. Kneip, T. J. and R. E. Hazen, "Deposit of Mobility of Cadmium in a Marsh-Cove Ecosystem and the Relation to Cadmium Concentration in Biota," Environ. Health Persp., 28: 67-73 (1979).

2. O'Connor, J. M., T. J. Kneip, G. Nau-Ritter, "Chemical Ecology of the Hudson-Raritan System: Sources and Transport of PCBs from the Estuary to Coastal Waters," presented at "Ocean Pollution 81," Dalhousie University, Halifax, Nova Scotia, Canada.

3. Kneip, T. J., J. M. Daisey, J. J. Solomon and R. J. Hershman, "N-Nitroso Compounds: Evidence for the Presence in Airborne Particles," Science (in press).

Bibliography

1. Daisey, J. M., T. J. Kneip, I. Hawryluk and F. Mukai, "Seasonal Variations in the Bacterial Mutagenicity of Airborne Particulate Organic Matter in New York City," Environ. Sci. & Technol., 14: 1487-1490 (1980).

2. Samolloff, M. R., J. Bell, D. A. Birkholz, G. R. Barry Webster, E. G. Arnot, R. Pulak and A. Madrid, "Combined Bioassay-Chemical Fractionation Scheme for the Determination of Ranking of Toxic Chemicals in Sediments," Environ. Sci. & Technol., 17(6): 329-334 (1983).

3. Kneip, T. J., et al., "Management of Non-Point Sources," pp 145-161, In: Ecological Stress and the New York Bight: Science and Management, G. F. Mayer, ed.,Estuarine Research Federation, Columbia, South Carolina (1982).

4. O'Connor, J. M., J. B. Klotz and T. J. Kneip, "Sources, Sinks and Distribution of Organic Contaminants in the New York Bight Ecosystem," pp. 631-653, In: Ecological Stress and the New York Bight: Science and Management, G. F. Mayer, ed., Esturarine Research Federation, Columbia, South Carolina (1982).

5. Kneip, T. J., "Summary of Management Panel Findings," presented at Symposium on the Ecological Effects of Environmental Stress, New York, N.Y. June, 10-15, 1979.

6. Kneip, T. J., "Public Health Risks of Toxic Substances," Chapter 9, In: Ocean Discharge of Municipal Waste: Impact on Coastal Waters, E. Myers, ed., MIT Sea Grant, Cambridge, MA 02139.

NEW YORK UNIVERSITY MEDICAL CENTER
A private university in the public service
Institute of Environmental Medicine
550 FIRST AVENUE, NEW YORK, N.Y. 10016
AREA 212 340 7300 ext 885-5231 or 914-351-5355
ANTHONY J. LANZA RESEARCH LABORATORIES AT UNIVERSITY VALLEY
LONG MEADOW ROAD, STERLING FOREST, TUXEDO, N.Y. 10987
MAIL AND TELEPHONE ADDRESS: 550 FIRST AVENUE, NEW YORK, N.Y. 10016

October 21, 1983

Senator Dave Durenberger
Chairman
Subcommittee on Toxic Substances
and Environmental Oversight
United States Senate
Committee on Environment and Public Works
Washington, D.C. 20510

Dear Senator Durenberger:

Thank you for the opportunity to testify before your subcommittee. Your interest in environmental problems and that of your committee members is greatly appreciated.

The answers to your questions are attached. If I can be of any further help please call on me.

Sincerely,

Theo. J. Kneip

Theo. J. Kneip, Ph.D.
Deputy Director
Laboratory for Environmental Studies

TJK/emcc

Enc.

SESQUICENTENNIAL 1831 1981 CELEBRATION

Question 1a. You were a member of a Governor's Committee on PCB problems in New York State; could you describer the kinds of information about PCB's that were not available to you that might have helped environmental chemists detect, monitor, and evaluate the risk posed by the chemical?

The early information available on the Hudson River PCB problem was quite sketchy. Latter evaluations were based on considerably more data on levels of PCBs in fish. This is not unusual in the early stages of a newly discovered problem and often is simply unavoidable from the point of available funds and effort in the early stages.

However, the estimates of risk were and are based on actual exposures of humans or laboratory animals to mixtures of PCB isomers as produced or as used by industry. The mixtures present in aquatic systems, including food fish, have been modified by metabolic processes and normally no longer contain the mono, di or tri chloro isomers. It was suggested many years ago that the mixtures in food fishes be isolated and retested in animals in parallel to normal industrial mixtures to determine whether the metabolic processes had modified the toxic properties of the mixtures. To my knowledge this has not been done. It is possible that the toxicity is much lower for metabolized PCBs, where little or no further production of metabolites would occur after subsequent exposure of a mammal.

Question 1b. It is your experience that these kinds of information are today typically available for environmental contaminants? That is, with TSCA, RCRA, and the other environmental statutes, do you feel confident we are today prepared to anticipate and prevent repeats of PCB-type incidents?

While not all desirable information is assured by TSCA, RCRA, etc., existing data and state and Federal regulations make long term discharges and unexpected environmental accumulations of hazardous materials very unlikely under normal business procedures. It would seem to me that deliberate intent or total ignorance would be required to reproduce the cadmium. mercury and PCB accumulations seen in the New York area, or any others like them.

As I pointed out in my testimony a failure of enforcement can negate this conclusion. This is the case for uncontrolled discharges to sewage treatment systems which then discharge the toxic materials in their effluents or sludges. Accumulations of toxic materials may then be found in aquatic sediments and sludge dumps whether on land or at sea.

Question 2. Are there any recent scientific findings that would justify a requirement of confirmed evidence of harm to a human population before EPA acts to control a chemical that shows tumor-causing effects in animal experiments? Or put another way, should current policies still presume that any chemical showing tumor-causing effects in animals is a potential human carcinogen and should be regulated as such?

> The precise prediction of the quantitative outcome of human exposures cannot be made on the basis of animal exposures. It is even possible that an occasional compound negative in animals may be positive in humans and *vice versa*; however, these latter events are not highly likely.
>
> Since the results of human exposures may require 15 to 30 years to detect and are irreversible at that point, it would seem foolhardy in the extreme to ignore valid positive animal test findings of carcinogenicity. The impact of industrial chemical exposures has been greatly exaggerated in some estimates, nevertheless the suffering of only a few deliberately exposed humans cannot be justified in the face of valid animal results.

The Regulation of Toxic Chemicals in the Environment

by

Dr. William Cooper
Department of Zoology
Michigan State University

Prior to the 1970's public institutions responded to episodes of toxic chemicals in the environment only after the fact. The mode of operation for environmental organizations was to find impacts of pollution, identify the source and then attempt to sue the pollutors. Two major events occurred in the early 1970's that challenged the validity of our feedback response system. Polybrominated biphenyls (PBB) was accidently introduced into the feedstock for dairy cattle in Michigan in 1973. Kepone, a chlorinated insecticide, was intentionally discharged in large quantities into the James River, Virginia, between 1971 and 1975. Both of the halogenated compounds are persistant, highly toxic and accumulate in human and ecological food chains.

In both cases, the attention given to the economic, social, political and environmental impacts by the media generated a ground swell of public opinion that these situations should be prevented in the future. The wait and watch mentality of the past was obviously no longer socially acceptable. The people in Michigan and Virginia experienced massive social and economic damages. Fears of long range human health effects generated personal anxieties. The time lags in response of governmental institutions from when we first observed workers with the "Kepone shakes" and cattle with physical and behavioral deformities were months and years. The data required by the regulators to justify an aggressive response was not available. Analytical chemical techniques needed to be developed. Acute and chronic toxicity tests needed to be performed. Action or tolerance levels needed to be established.

In the meantime, both episodes appeared on "60 Minutes" in all of their gory details. Life Sciences Products declared bankruptcy, Michigan Chemical denied any involvement and both parent companies (Allied Chemical and Velsicol) claimed no responsibility or liability. The damages in both cases eventually totaled into the hundreds of millions of dollars and we still do not know the long range human health impacts.

The feedback response system requires an error signal to trigger a regulatory action. With chemicals that are toxic, persistant and bioaccumulate in the environment, the cost of being wrong is socially unaccpetable. The passage of the Toxic Substance Control Act in 1976 was in part motivated by our experiences with Kepone and PBB. A major shift in logic involved the requirement to perform risk assessments prior to the manufacturing of a compound. Risk assessments involve testing for toxicity, estimating exposure concentrations in the environment, and calculating potential damages to the environment and human health if the compound is mishandled. The anticipated errors are then evaluated in terms of economic and social acceptability. This aspect of TSCA is essential for environmental protection.

The data required to perform ecological and human health risk assessments are often difficult and expensive to obtain. The models used to estimate exposure concentrations are based upon very restrictive assumptions. The transfer of laboratory toxicity tests to field situations involves much uncertainty. The variation in sensitivity of different species including humans to a given toxicant requires the use of unverified safety factors. The list can go on, but this is the best science that is currently available. The economic cost and uncertainties experienced by industry in attempting to conform to the testing requirements of TSCA are real. On the other hand, the costs and uncertainties of society from the Kepone and PBB episodes are much greater. The estimated clean-up of Kepone from the James River ranged from 3 to 13 billion dollars and none of the alternatives are socially or ecologically acceptable. Michigan spent over 400 million dollars recovering from PBB, the landfill site which received PBB waste is our first superfund project and the human health impacts are still unknown.

There exists considerable concern among environmentalists that the testing and risk assessment opportunities provied by TSCA are not aggressively utilized by either EPA or industry. Much of the activity since 1976 has been directed at the development of test protocols, field validation of laboratory results, development of computer models for estimated exposure concentrations and statistical models for risk assessment. These developments are also essential to the process of establishing permitted discharges of toxic chemicals into the air and surface waters. Often the toxic compound is not the parent product but either a contaminant or a reaction product associated with the process.

In Michigan we are currently establishing permitted levels of known mammalian carcinogens to be discharged into surface waters (Rule 57). These levels are based on ecological and human health risk assessments and not on the best available technology approach that is generally utilized. As we advance to biologically based environmental standards, the technologies developed under TSCA will be utilized in a wide array of regulatory activities.

It is essential that TSCA continues as a major part of our regulatory strategy. Without these requirements for biological toxicity tests, definition of chemical characteristics and risk assessments there is little incentive for industries to carefully examine their processes and products. Emphasis should continue to be focused on chemicals that constitute high risks. EPA should be encouraged to aggressively utilize their powers under TSCA to prevent future episodes of major environmental contamination.

STATEMENT OF

DON R. CLAY
ACTING ASSISTANT ADMINISTRATOR
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE

SUBCOMMITTEE ON TOXIC SUBSTANCES
AND ENVIRONMENTAL OVERSIGHT
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

JULY 27, 1983

Good morning, Mr. Chairman and members of the Subcommittee. I am pleased to have the opportunity to testify before you today concerning the problem of toxic substances in the environment and to describe part of EPA's program to evaluate and if necessary control those substances.

I am here as the Acting Assistant Administrator for Pesticides and Toxic Substances. As you are aware, this is a time of transition at EPA. Administrator Ruckelshaus is in the process of installing his Senior Management Team. Over the next few months, I'm sure he will be addressing a variety of policy and legislative issues, including those dealing with toxic substances. I hope that my remarks today can help set the stage for what I believe will be a renewed EPA emphasis on a strong innovative toxic substances program for the future. With your permission, Mr. Chairman, I would like to submit my written testimony for the record and spend just a few minutes of your time highlighting the progress of the Office of Pesticides and Toxic Substances' toxic substances program as well as my views on that progress.

Background

The Office of Pesticides and Toxic Substances regulates toxic substances primarily under two laws: the Federal Insecticide, Fungicide, and Rodenticide Act (or FIFRA) and the Toxic Substances Control Act (or TSCA). The Office of Pesticides and Toxic Substances also establishes pesticide tolerances of legally acceptable residue levels under the Federal Food, Drug and Cosmetic Act, but I will limit my discussion today to the FIFRA and TSCA. Together these laws allow EPA to evaluate and if necessary limit the ways in which a chemical can be used in order to protect human health or the environment. Under these laws EPA has authority to collect information about chemicals - such as how much is produced and where; how many people are exposed; what is known about the chemical's toxicity; and environmental effects and how the chemical is being used. If necessary, based on this information EPA can safeguard public health or the environment by controlling the chemical at the most appropriate stage, whether that involves banning it completely, controlling initial manufacture, putting conditions on use and disposal practices or anything in between.

FIFRA and TSCA have more in common, however, than their authorities to gather information, evaluate, and control. Both were initially written by Congress as risk-benefit statutes. This balancing of risks and benefits underlies the regulatory decisions of both laws. This means that when evaluating a chemical, whether as a pesticide or a chemical bound for other industrial use, EPA must determine whether that chemical can perform its intended function without causing unreasonable risks or unreasonable adverse effects. The concept of unreasonableness reflects a judgment that the probability and magnitude of harm to society from the use of a chemical is likely to outweigh the benefits. The benefits are determined by the uses to which the chemical is put, as well as by the profits and employment due to its use. The risks depend on the degree of certainty that the chemical poses an adverse health or environmental hazard, the nature of the hazard, the probability of risk to a given individual or group of individuals and the number of people exposed.

While there are similarities between TSCA and FIFRA, there are also differences. FIFRA is basically an approval or a licensing law. A pesticide cannot be used until it is registered by EPA. Each use must be registered. Pesticide labeling establishes the conditions of use for a pesticide. Any use in a manner inconsistent with the labeling is prohibited by law. TSCA on the other hand, takes action on a chemical only when public health or the environment would suffer if that action were not taken; and only if actions under other laws or by other federal agencies are not forthcoming. In other words, under FIFRA, EPA has complete responsibility for approving and regulating a specific subset of chemical substances (pesticides), while TSCA was designed to be a gap filler, designed to allow EPA to gather information in anticipation of potential problems and take action when other laws are insufficient. I would like at this point to turn to a description of program goals and accomplishments under each of these two laws. The description of the pesticides program will be considerably more brief than that of the toxics program. At the Committee's request, I am emphasizing the TSCA program to provide the foundation for TSCA reauthorization hearings in the future.

FIFRA

Pesticides are substances used to kill or control unwanted insects, plants, fungi, mites, rodents, bacteria, or other pests. Approximately 50,000 such products - derived from about 600 basic chemical ingredients - are currently registered for use by EPA. These products range from the common household bleach to sophisticated chemical formulations designed for use on speciality crops. By their very nature, the purpose of a pesticide is to kill or affect the behavior of some living thing. The 600 basic chemical substances in pesticides (representing one hundredth of the approximately 60,000 existing chemical substances) require careful scrutiny to assure that their use produces the desired effect - pest control without endangering human health or the environment.

Pesticides regulation has always been controversial. Given the range and number of important societal interests at stake, scientific uncertainties and the serious consequences for health, the environment, agriculture and property that flow from regulatory actions, there will always be differing viewpoints on how to regulate individual pesticides as well as on overall policy objectives.

Looking at the program simplistically, there are two major functions in the Office of Pesticide Programs: acting on applications for registration of new chemicals and products and new uses of old chemicals, and reexamining previously registered products to ensure that they meet today's scientific standards.

The building block for both programs is the base of data on the characteristics and effects of pesticides. One of EPA's first actions was to decide what scientific data were needed to make responsible decisions on pesticide products, and what data already existed in Agency files.

Data requirements

As the Committee is aware, FIFRA was significantly amended in October 1972 to change its emphasis from product performance to human and environmental safety. EPA developed its first basic set of data requirements in July 1975. Based on the experience gained with these basic requirements over the intervening eight years, EPA most recently proposed much more comprehensive and detailed data requirements in November 1982. These data requirements set forth what data will be required to register various types of pesticides for different uses. Detailed Guidelines on how to conduct the required studies which were printed in February 1983 are available for viewing at State and Federal offices, and may be purchased from the National Technical Information Service.

Registering New Chemicals, Products and Uses

As a result of the 1972 amendments, applicants for registration were required to identify what data supported their products' registrations. EPA was obligated to review the data base identified for each product even though this resulted in multiple reviews of essentially the same data base, since the Agency received many applications for products containing the same active ingredients.

In 1975, EPA issued, as required by the 1972 amendments, final regulations for the registration, reregistration and classification of pesticides. These regulations were essentially a comprehensive statement of data requirements for registration which had been developing during the early 70's in light of modern scientific standards and knowledge of pesticides' acute and chronic effects. However, their promulgation created a "double standard" in registration. Products registered after 1975 had to meet the new, more stringent data requirements of the regulations even though similar or even identical products registered prior to 1975 were generally supported by a much smaller data base.

Thus, in 1977 the Administration proposed, and in 1978 Congress enacted, additional major amendments to the FIFRA which relieved the inequities of the existing system. The 1978 amendments permitted conditional registration of new products even though the data base might not fully satisfy data requirements for registration. All registrants of like products would have to provide the missing data at a time specified in the future. Conditional registration also freed Agency resources from multiple reviewing of the same data and permitted it to concentrate on data review for reregistration.

Finally, the 1978 amendments sanctioned a chemical-by-chemical, rather than product-by-product approach to registration (and reregistration). This registration standard approach will ultimately simplify registration for both the Agency and registrants.

Emergency Exemptions

The 1972 amendments authorized EPA to issue emergency exemptions and the Agency issued final regulations implementing this authority in December 1973. The requesting States submit to EPA information demonstrating that a pest control emergency does exist which cannot be met by the use of federally-registered products and information on the emergency control program they are proposing - including the method, rate, area and duration of application of the emergency use pesticide. EPA reviews the risks and benefits of the proposed emergency use in light of available hazard data as well as potential economic or other loss if the pest is not controlled. The final decision depends upon the balance of risks and benefits. Until recently, the Agency received approximately 300-500 emergency use requests per year. In the past two years, the numbers have risen considerably. We have just completed an audit of the emergency exemption program of the past 5 years, which has been made available to the Congress, the States and the public. We will be exploring with the States and the public what changes may be necessary in our regulations as a result of the findings of the audit.

State Registration

FIFRA also permits States to register additional uses of federally-registered pesticide products to meet special local pest control needs. EPA retains the right to disapprove these State registrations within ninety days of issuance, but only under very limited circumstances. The Agency reviews about 1,200 - 1,700 State registrations per year and to date has agreed with almost all of them.

Review of "Old" Chemicals

Special Review

When Congress amended FIFRA in 1972, it required EPA to undertake a monumental task: to review all chemicals already on the market and reregister them against today's scientific standards.

This has not been an easy task. The Agency has pursued a deliberate long-term strategy for reviewing these old chemicals, dealing first with identified problems, obtaining new data on chemicals with inadequate data, and curtailing uses, changing labels, and/or reaffirming as appropriate previously approved uses of existing chemicals.

In July 1975, the Agency issued its final regulations which established criteria for identifying what pesticide effects the Agency would presume to be unreasonable - effects such as cancer, birth defects, and mutagenic effects. The presumption could be rebutted by showing that the effects data were not valid, the risks could be reduced, or the benefits exceeded the risks. The process was thus called rebuttable presumption against registration or RPAR. Thus since the RPAR process became operational in early 1976, it has been, in fact, an informal and thorough review process for both risk and benefit information on a pesticide which meets or exceeds the RPAR risk criteria. The results of the RPAR decisions illustrate the variety of actions which can be taken in coming to grips with potential problem pesticides while recognizing both risks and benefits. A number of pesticides have come off the market, many voluntarily, as a result of the regulatory program. Many other decisions have resulted in some uses being cancelled while others are retained under more stringent use restrictions. Still others have been dealt with by imposing restrictions across the board to reduce risks to acceptable levels. In some RPAR's we have found the data base to be so inconclusive that the primary action is to require the generation of data to answer the questions in an informed way. Still others are found to require only minor changes because the review concluded that the existing uses do not pose unreasonable adverse effects, taking into account actual and/or potential exposure.

A common criticism of the pesticides program is that there were many more RPAR's issued several years ago than there are now. The fact of the matter is that EPA has achieved much of its original purpose by dealing with most of those older existing pesticide registrations that were identified as potentially posing an unreasonable risk. The newer pesticide registrations, having fuller, more recently developed data bases, are less likely to give rise to an RPAR proceeding. Therefore it would be very unusual if the number of RPAR's initiated continued to be high, since the process is designed to correct the errors or problems of the past. Additional RPAR candidates are, of course, expected to emerge from the now ongoing data-generating efforts being required of registrants of existing chemicals with incomplete data bases. However, I think it is important to realize that the Agency is coming to an end of a most significant first major step in catching up with and reviewing 25 years' accumulation of previous pesticide decisions as directed by Congress.

Registration Standards

The second major effort with respect to existing pesticides is to review the remainder of old chemicals which have not been singled out as potential problems or as especially risky in the Registration Standard program. Reregistration has progressed by fits and starts. The original scheme for reregistration in the early 70's assumed that most data on file were valid and properly reviewed and that any problems with the data had previously been identified and resolved. Thus the Agency review of data on hand had focused on identifying data gaps, not on validating the existing data. However, in 1976, discussions with FDA and GAO, Senate hearings, and the Agency's own internal operations review raised serious questions about the adequacy of test data in EPA files and the completeness of the Agency's own review and follow-up. The 1978 amendments to FIFRA were designed, in part, to address this problem. These amendments allow the Agency to make a comprehensive review and decision per pesticide active ingredient rather than multiple individual decisions for many products containing the active ingredient. This new authority has enabled the Agency to concentrate resources on the review of potential risks to man and the environment, and thereby substantially shorten the length of time necessary to accomplish reregistration.

The current approach results in the development of a Registration Standard for a pesticide chemical which sets forth the conditions for reregistration of old products and registration of new products. The processing of registration application involves a straight-forward decision whether the conditions of the standard have been met. To date, approximately 58 standards have been issued with about 6 more expected by the end of fiscal year 1983. The Agency is using a cluster approach to the development of standards so that chemicals with like uses are reviewed at the same time. Clusters have been ranked so that high volume and food use pesticides are addressed sooner rather than later, although some of the early standards were developed on small volume chemicals, selected principally to develop and test the process.

Extent of Data Base

One of the key questions in doing a Registration Standard is whether the chemical in question has an up-to-date data base by today's standards. We estimate that for most chemicals registered prior to the 1975 data requirements the answer is "no." This is not to impugn pesticide registrants - it is primarily a reflection of the fact that data requirements have increased over time and many products were registered in earlier years when fewer requirements were in place. EPA has discovered, not surprisingly, that the early Registration Standards have resulted in the need to call new data from pesticide manufacturers.

Quality of Data Base

Review of data for Registration Standards also focuses on the quality of the studies in our files. Data gaps occur not only where data just doesn't exist, but also where data exists but is invalid or inadequate.

The scandal associated with Industrial Biotest Laboratories (IBT) shook both the industry and the public. It underscores the need for scrutiny of old studies, and for constant vigilance in reviewing incoming information.

The discovery of hundreds of questionable health effects studies conducted by IBT created a massive problem for EPA and Health and Welfare Canada. We responded by developing a cooperative validation review program to determine the status of each significant health effect study conducted by IBT. On July 11, we released a report summarizing the current status of the joint EPA/Canadian review. Copies of this report have been supplied to Congress.

In general, we found that high volume use chemicals tested by IBT, which present the highest potential for exposure to pesticide users and the general public have been largely accounted for in terms of available alternative data or commitments to replace IBT studies. Many of the approximately 35 pesticides most likely to receive our notifications this summer appear to be minor use products for which registants will not contest suspension rather that invest in further testing. At this point it appears that the uncertainties caused by invalid IBT studies have been brought under control and are well on their way to being resolved. It also does not appear that these uncertainties masked hitherto unsuspected health hazards to a significant degree, as some had feared.

This abbreviated description of the pesticide program under FIFRA obviously omits many of the complexities associated with implementation of the law. However, the key aspects of the program have been discussed and I want now to turn to a similar description of the toxic substances program under TSCA.

TSCA

Before I go into detail on the TSCA approach to toxic substances evaluation and control, I want to point out one obvious difference between the TSCA history and that of FIFRA. As you have heard, FIFRA was originally passed in 1947, over 35 years ago. During that time the law changed from being an efficacy law to a health protection law, a change which was effected through a series of amendments. By contrast, TSCA became effective in 1977. For the first several years, most of the EPA effort was spent hiring staff and developing procedures. When I became Director of the Office of Toxic Substances in 1981, proposed regulations and policies were at a baseline level, that is, the program had only the rudiments in place for a full-fledged environmental and public health protection program. One of my first actions was to begin an intense study of TSCA implementation so that operating priorities for the program could be set. These priorities were printed in January 1982 in a report we call the "100 Day Report."

As a result of that effort, we have begun to use most sections of the law. We're getting more experience with the law's provisions and our learning curve is leveling off. However, I would be less than candid if I did not say that we are still feeling our way in some areas. In a year or so, I believe we will have exercised all of TSCA's authorities and will have enough experience to be able to identify areas where change in the law could provide additional health and environmental protection. TSCA gives EPA general authority to regulate manufacture, distribution, and use of harmful chemicals. Congress enacted TSCA in recognition of what it perceived to be loopholes among existing statutes that were limited in scope to a specific environmental problem (for example, an air quality or a water quality problem) or to specific settings or products (for example, a workplace setting or in a consumer product). In addition, Congress was concerned that new chemicals could be manufactured and enter the environment without any government review of potential harmful effects. And finally, Congress wrote into TSCA sweeping authorities to collect both scientific and economic data about chemicals. These data, Congress hoped, would begin to build a centralized base of information to support sensible and effective chemical regulations.

While these authorities are sweeping, Congress did not intend that they be used in a vacuum. TSCA is definitely a risk-balancing statute. Section 2 of TSCA requires EPA to carefully consider the impacts of its decisions and to assure that they do not unduly impede or create unnecessary barriers to technological innovation. Further, this section of the law states Congressional intent that EPA consider three primary impacts of any action - environmental, economic, and social. As the Commitee well knows risk/benefit analysis is a complex and difficult process, but it is inherent in every decision made under TSCA.

In addition to the risk-balancing aspects of the statute, there is another unique feature of TSCA which sets it apart from many other environmental laws. Since TSCA authorities are chemical-specific and can be used to address a chemical wherever it is found - the air, the water, a dumpsite, the workplace, in a product and so forth - the potential for TSCA action duplicating or confusing the efforts of other EPA programs or other Federal agencies is high. Thus Congress directed EPA to coordinate with other Federal programs; to share information and risk determinations, and to defer action to other laws when authority to take action exits elsewhere. Our actions to date have resulted in a variety of cooperative programs. For example, we are regulating the disposal of PCB's with the expectation of turning over those regulations to RCRA once their regulations become final. We have asked the Occupational Safety and Health Administration to work with us on a regulation for a chemical which appears to present risks only in the workplace. We are coordinating with several other Federal agencies in consideration of appropriate regulatory actions concerning asbestos.

While I believe that we have made a credible beginning in the area of coordination and integration with other Federal programs, I also am committed to doing more in this area. I do not view TSCA's referral mechanism as an opportunity to avoid action, but rather as an opportunity for coordination. I have instructed my staff to consider ways in which TSCA's information gathering authorities can be used for the benefit of other EPA program offices. I think we can do a better job of facilitating public access to chemical data, once it is collected. The involvement of other EPA programs in the development of actions taken under TSCA and the involvement of my staff in other EPA actions should be greatly expanded. This cross fertilization I believe is crucial to achieving an integrated approach to toxic substances control and I expect to devote significantly more attention to this effort in the future.

Having laid out the unique aspects of TSCA and given you my thoughts on how I intend to take advantage of them in the future, I would like to turn now to a discussion of the three major authorities inherent in the law. These are: data collection, review and evaluation of new chemical substances, and reduction of exposure to existing chemical substances.

Data Collection

TSCA contains authority for gathering two basic types of information: chemical production and use information, and data from health and environmental effects testing.

Section 8 of TSCA includes several reporting requirements for production and use information. Until TSCA was passed, there was no centralized list of every chemical known to be in current production or being imported into the United States. Section 8 required EPA to establish such a list, which contains each chemical's scientific nomenclature, and production statistics. This chemical inventory was first published in 1979 and new chemicals have been added as they go into production. The inventory now includes basic information on nearly 60,000 existing chemicals. We use the inventory constantly, for example, to determine if a new chemical is really new and to assist in estimating exposure potential for chemicals. The inventory is also useful to other EPA programs and States to identify plant sites, or track down causes of chemical contamination problems. While this list is useful, the original 1979 statistics are becoming outdated. As a result, I have decided to update the inventory, and have directed my staff to evaluate alternative ways that could be used.

In addition to the inventory, TSCA allows EPA to collect even more information if we need to make decisions about chemicals and need more information to do so. This information can include chemical identity, proposed uses, estimates of production levels, description of byproducts, health and environmental effects data, and worker exposure. A final rule requiring submission of this type of production and exposure data for 250 chemicals was published in June 1982, and is automatically updated twice a year to add additional chemicals we are reviewing.

Other subsections in TSCA's Section 8 allow EPA to require companies to submit scientific data or reports of adverse health effects which otherwise would be unavailable to EPA. For example, a final rule was published in September 1982 requiring manufacturers to submit unpublished health and safety studies on specific chemicals. As a result, approximately 4300 unpublished health and safety studies have been received. Another subsection of Section 8 requires manufacturers to notify EPA when they receive information that any chemical may present a significant risk to health or the environment. Substantial risk notices are being received at a rate of approximately 70 per year. In a number of cases, submission of these final notices has also resulted in the company instituting voluntary risk reduction measures such as use of protective equipment for workers. These studies and data are being used both in our decisions about which chemicals warrant additional testing or control action and in decisions about priorities in our existing chemicals program.

There is one provision in Section 8 which has not been implemented to date. That is the section of the law requiring manufacturers and processors to keep records of significant adverse reactions to health or the environment that allegedly were caused by the chemical. Records concerning health effects on employees must be kept for 30 years; other records for five years. A final rule implementing this provision reached the

Administrator last week. I would also like to mention that the Administrator's Toxic Substances Advisory Committee provided a very useful forum last fall for obtaining reactions to the final concept of this record-keeping rule. We are already working closely with labor and environmental organizations to make them aware of this new opportunity for workers to record allegations of adverse chemical effects.

Chemical testing is the second major source of data for EPA and authority to require such testing is embodied in Section 4 of TSCA. No other regulatory agency can require manufacturers to test industrial chemicals for a full range of human health or environmental effects. Section 4 authorizes EPA to require chemical manufacturers to test specific chemicals, categories of chemicals, or mixtures for potential health and environmental effects. To require testing, EPA must first find that the substance either may present an unreasonable risk or it is or will be produced in quantities which may result in substantial environmental release or human exposure. Second, EPA must find that data are insufficient to evaluate the chemical and that testing is necessary to develop data concerning potential adverse effects.

TSCA also establishes a priority-setting mechanism to ensure that chemicals are systematically identified and evaluated for testing decisions. Section 4(e) sets up an Interagency Testing Committee (ITC), composed of representatives from the major Federal agencies concerned with health and the environment.

This committee designates substances for priority EPA consideration as to whether testing is needed. EPA must respond within 12 months to a chemical's designation, either by requiring testing or by publishing in the Federal Register its reason for not doing so.

The chemical testing program in OTS got off to a slow start in TSCA's early years. The Agency failed to meet the first five statutory deadlines for responses to ITC designations. This lack of action caused a lawsuit in 1979 which resulted in a court schedule for Agency responses to 37 backlogged ITC designations. Consequently, in 1981 when I arrived, the Agency had not only a backlog of chemicals to assess but also had to meet the one-year statutory deadline for current ITC designations.

In addition to my commitment to meeting these deadlines, I have emphasized the importance of developing needed test data rapidly, so that potential risks can be identified as soon as possible. As a result, in certain cases we are negotiating testing programs with manufacturers or industrial consortia, if this will result in receipt of needed test data substantially sooner than would be the case if we proposed test rules.

I would like to emphasize that while we see negotiated testing agreements as an effective way to speed receipt of test data, we do not believe that all chemicals are appropriate for negotiation. Certain general factors, such as multiple manufacturers or the magnitude of testing needed or complex issues which prevent agreement, all may tip the scale toward rulemaking. In responding to the original court schedule for addressing the backlog, the Agency picked the easiest ITC chemicals first. Many of those lent themselves well to the negotiated process. However, many of the remaining chemicals do not. In total, by the end of calendar 1983, OTS anticipates proposed test rules on 11 substances, reaching testing agreements on 19, and decisions on 12 others that testing is not required at this time.

One final note on testing as it applies to data collection. By January 1984, the ITC backlog will be eliminated. We will then be able to use other internal machanisms to identify candidate chemicals for testing. Again, because TSCA is a relatively new law, and because we were addressing both backlog and current ITC designations, we have not been in the position to use information from other TSCA provisions to decide chemical testing needs. Areas where we can get high priority chemicals for testing consideration include: substances with significant human exposure which have been identified through monitoring activities or by others as important, classes of substances identified as potential concerns in the new chemical review process, and chemicals for which exposure currently isn't enough to warrant testing but which might if production increased. An example of this latter category are ITC chemicals where we have decided not to require testing because of low production or highly limited exposure and release. A possible alternative response to no testing in such cases is to develop "triggered" testing rules that would take effect only when production volume, exposure, or release criteria contained in the rule were exceeded.

Review and Evaluation of New Chemicals

I would like to turn now to the second major authority under TSCA - review and evaluation of new chemical substances. As I'm sure you know, TSCA's Section 5 gives EPA authority to review all new chemicals before they are manufactured. This provision called premanufacture (PMN) review, was written to address Congress' concern that a seemingly beneficial new chemical could be introduced into the marketplace and achieve widespread use without governmental review and before adverse health or environmental effects became appparent. By law, EPA has 90 days to review a new chemical. If EPA takes no action the manufacturer is free to commercialize the chemical. However, EPA can restrict or stop commercialization entirely if there are concerns about a chemical's health or environmental effects.

Since beginning the new chemical program in mid 1979, the Agency has reviewed over 2500 premanufacture notice submissions. The rate of receipt has continued to climb each year, and we are now receiving an average of 100 new chemical notices to review per month.

In reviewing a new chemical, EPA assesses the exposure to the chemical throughout the chemical life cycle. This includes an assessment of potential human exposure in the industrial, commercial and consumer setting; and an analysis of environmental fate where we predict potential releases to receiving streams, and persistence in soils and sediments. This information, in conjunction with the predicted production volume, allows us to assess the potential exposure to a new chemical. The emphasis of the EPA PMN program has been on systemic and chronic effects both human and environmental. EPA combines data on manufacturing use, processing, and exposure with data from literature searches, additional data submitted by manufacturers, and data on chemical analogues.

EPA has begun to request additional test data on specific new chemicals from submitting companies as early as day 16 of the 90-day review process. Our experience in reviewing the 2500 PMNs is that in the majority of cases test requirements are chemical-specific. If the company agrees to conduct testing, often the data can be developed and analyzed within the 90-day review period. If more than 90 days is required, generally, a company is willing to suspend the PMN review period and to postpone manufacture of its new product while testing is being conducted. If not, EPA can issue an order prohibiting production until information is received. As long as the review period has not expired, EPA retains authority to require additional information or to regulate the PMN chemical, based on the outcome and analysis of the company's testing.

In its almost four years of new chemical review, EPA has gained valuable experience that has led to a more effective review of new chemicals, allowed refinements of the current program, and indicated directions for further development.

Biotechnology

One final example of future action in the new chemical program concerns the area of biotechnology. Biotechnology has until very recently been a laboratory-scale phenomenon; however, commercial uses potentially subject to TSCA regulation are now under development. Significant risks may be associated with some of these uses of biotechnical substances, particularly as a result of their release into the environment. TSCA offers a sound mechanism for the evaluation of potential risks from biotechnology. OPTS is mounting a broad effort to ensure that health and environmental risks posed as a result of TSCA uses are appropriately characterized and controlled.

Follow-up Program

Thus far, I have been discussing the process for EPA's review of a new chemical. In addition to refining that process, we have a relatively new complement to the PMN review that I believe also protects public health and the environment from potential adverse effects of new chemicals. The new program monitors chemicals which complete the PMN review but about which EPA may have further concerns should their use or exposure change. We call this our "follow-up" program. We take follow-up actions if we have concern about a chemical's toxicity and have identified possible changes in exposure which could lead to increased risk. As of a year ago, 183 PMN chemicals were backlogged for follow-up consideration. However, none of these chemicals had been further reviewed and no chemicals had been identified for follow-up

More new chemicals than ever are going into detailed review. More conditions are being put on the use of new chemicals and the exposure of workers during manufacture. Additional steps taken to improve the program include the development of the final PMN rule and modification and refinement of the PMN review process. When the final PMN rule becomes effective it will provide industry with clear standards for compliance, simplify EPA's review of new chemicals, and promote consistency. With respect to modification of the PMN review process, refinements have also been instituted or are now under development. For example, we have proposed exempting certain categories of low risk chemicals from the full 90 day EPA review. These exemption proposals contain strict safeguards and allow for adequate EPA assessment. I support these exemptions because they will reduce burdens on industry, allow earlier commercialization of low risk chemicals, and will not increase risks to health or the environment. Other refinements to the PMN process which we are developing include a new chemicals Advisory Circular system to summarize actions on specific categories of new chemicals or to describe specific PMN decisions. These circulars will publicly advertise situations where EPA will likely need more data in reviewing a PMN and as such will promote early submission of such data. We are also considering issuing Section 4 test rules on PMN categories of concern and using a "risk list" to require submission of additional test data for certain categories of new chemicals.

regulation. We made establishment of a viable follow-up program a priority. As of March 30, 1983, this backlog was reduced to 24 chemicals and the Agency is completing review of new additions to the list without creating a new backlog.

We have two unique tools in TSCA for following-up on chemicals after new chemical review is completed. Section 8's information gathering powers can be triggered when we feel more information is needed on uses, production volumes, description of by-products, health and environmental effects data, or exposure. Section 5 allows EPA to re-review a given chemical if it is used in a significantly different way from that originally described in the PMN submission, and in a way which would cause EPA concern. Circumstances of concern include major changes in type of use or exposure, and major production volume increases. In cases where health concerns exist but exposure under the current PMN use is low, we will issue "significant new use" rules or SNURs which require the manufacturer to present the chemical to EPA again for review prior to beginning that new use.

A variety of factors can flag a new chemical for follow-up. These include changes in production volume, changes in the formulation of a chemical (eg. wet to dry), changes from industrial to consumer use, change from site-limited to non-site limited, and others. I would like to describe two examples of changes warranting follow-up by EPA, one of which is chemical-specific and one which could be generic to all new chemicals. The first is a change from industrial to consumer use. One proposed SNUR would require EPA notification before two new chemicals, which are intended for use in industrial cleaners, are manufactured or processed for consumer use. The second illustration of follow-up action relates to a change in production volume. We are considering issuance of a rule, requiring any manufacturer of a new chemical to notify EPA when his production volume reaches a certain level. This level may depend on the class of chemicals. The notice would contain information on production, exposure, and potential risk - such as production volume, use, and available test data. The rule would provide the broad-based new chemicals follow-up missing in the current program, and it would place a limit on potential risk that could occur without EPA notification. We would be able to track new chemicals as they developed commercially, and in cases of concern, we would be able to take steps to require data development or to regulate specific chemicals before they were well established in the marketplace. This would provide a general safety net, allowing us to address potential new chemical concerns that were not anticipated during PMN review.

While there is much more to be said about our new chemical review program, in the interests of time, I will move to the final major authority in TSCA, reduction of exposure to existing chemical substances.

Existing Chemical Substances

One of the major objectives in the TSCA program during the last two years was to get the existing chemicals program off the ground. We found that one of the major problems with the program was that there was no internal structure to review, prioritize and efficiently assess problems with chemicals in commerce under TSCA jurisdiction. Also, there was no method of bringing these chemicals to the point of making a decision about them. They remained in the assessment process interminably. The program was stalled trying to rank all existing chemicals on a spectrum so they would know which ones to address first.

Recognizing these problems, last fall I set up an Existing Chemicals Task Force within the Office of Toxic Substances to develop a process to begin working on existing chemicals. I decided that rather than try to rank all existing chemical substances, I would begin action on those we knew needed controls because of information already available. Postponing action on known hazardous chemicals until we knew exactly where in a ranking scheme they would land didn't seem to be sufficiently protective of health or the environment. The Task Force operates according to a set of priorities. Attention is focused on existing chemicals 1) for which Section 4 test data has been received; 2) on which substantial risk notices have been filed; 3) on which other test data have been received from such sources as the National Toxicology Program or Citizen petitions; and 4) for chemicals or categories of chemicals which consistently raise concerns during PMN review and which are similar to categories of existing chemicals. The Task Force to date has conducted (or is now conducting) reviews of 60 substances, identified through the mechanisms above. About one-fourth of these substances have been dropped from review. At the same time, about two-thirds are targeted for futher analysis. Five have already moved into regulatory development. The Committee might be interested in some examples of regulatory actions underway in this revitalized existing chemicals program.

We have issued an advance notice of proposed rulemaking on MBOCA, a curing agent used in plastics, which has been shown to be carcinogenic in several species of animals. Although the chemical is not now manufactured in the United States, some firms are considering domestic manufacture, and it is imported at 1-3.5 million pounds per year. The primary risks from MBOCA appear to be to plastics formulators, generally working in small establishments. There is no OSHA standard for this chemical, and no other Federal authority is directly addressing these risks. As a result, after consulting with OSHA, EPA has issued an ANPR suggesting a range of regulatory options, including a ban of certain uses of MBOCA, and asking the public to provide information and recommend alternative approaches. The reason for EPA action on this chemical, which is primarily a workplace concern, is TSCA's unique authority.

We have also initiated our first action under Section 4(f) of TSCA. Section 4(f) contains a process for priority accelerated review of chemicals suspected of causing serious or widespread harm to health or the environment. Under Section 4(f), EPA has 180 days to initiate rulemaking on the specific chemical or to publish reasons why regulatory action isn't necessary. The chemical designated for this priority review is MDA. MDA, a high-production volume chemical used primarily as an intermediate, had been designated for testing consideration by the ITC. However, a recent test conducted by the National Toxicology Program already indicates a serious potential to cause cancer; therefore, we have initiated priority review of the possible regulatory actions rather than wait for additional testing. Because MDA risks are primarily a workplace issue, the Office of Toxic Substances is coordinating its action with OSHA. The Section 4 mechanism has been critical in ensuring prompt regulatory attention to this potential hazard.

Looking forward in the existing chemical program, I have asked the staff to identify additional creative but effective ways to reduce exposure to potentially harmful chemicals. Some of these are already being used by the program and others are still being developed. In the interests of time, I will not discuss them all, but I would like to highlight a few examples. We are using Section 8 authority to alert us to changes in the production volume of one chemical, which has high hazard concerns but no current exposure, so that we can track exposures and if necessary take control action at the appropriate time. We also are using Section 5 authority to require manufacturers of specific chemicals to inform us of significant new product uses. This will allow us to control uses of specific chemicals which could adversely affect health or the environment. Several other mechanisms are in development and I will briefly highlight two of them. Among the TSCA authorities which have not been used to date is EPA's ability to get quality control information from industry. I intend to use this section of the law to better analyze manufacturing processes. Also, in the near future I expect to begin issuing Risk Management Advisories. Risk Management Advisories are focused on specific problems with specific substances and will be used to encourage meaningful precautions. These nonregulatory Advisories will describe toxic effects of concern, routes of exposure, and alternative methods of reducing risks; they will be published after consultation with interested parties, which could include industry, public interested groups, or other agencies. Risk Management Advisories will not be a substitute for rulemaking; however, they may in certain cases be issued in connection with rulemaking activities - for example, together with an ANPR - in order to alert industry and the public as soon as possible to potential risks.

I'm sure the Committee is familiar with our activities on well known existing chemicals such as PCB's and asbestos. I am not going to take time today to go into detail on these chemicals. However, I would like to highlight some recent events which you may find especially interesting.

With respect to PCBs, EPA has final regulations covering most aspects of PCB manufacture, use, and disposal. The remaining PCB rulemaking will deal with unintentional and incidental production of PCB's which occur in the process of producing other products. We were pleased to be presented with a proposal, developed jointly by the Natural Resources Defense Council, the Environmental Defense Fund, and the Chemical Manufacturers Association to address this aspect of PCB regulation. This evidence of often competing interests working together is something I would like to encourage in the future. My staff will use this proposal as the core of a regulation to be proposed by December 1983.

Asbestos has been the subject of OTS activities since the early years of the program. Recently, however, OTS has taken important steps toward consolidating its efforts toward asbestos and ensuring a coordinated approach by the various regulatory authorities concerned with this material. The establishment of an interagency Federal Asbestos Task Force to coordinate Federal efforts concerning asbestos has been a major achievement. The Task Force, which was established last year, is chaired by the Office of Toxic Substances, and includes representatives from OSHA and CPSC. Over the next year, my staff will be working with the Task Force to coordinate asbestos control.

In this regard, OSHA is working to strengthen its workplace standards for asbestos. Complementary to this activity, we plan to publish a proposed rule in the next year banning certain asbestos product categories and we plan to issue either an ANPR or a proposal which would establish a staged production cap on remaining asbestos uses. My staff is also pushing ahead this summer with a survey of asbestos in public buildings to assist us in determining the nature and extent of any problem with friable asbestos material in such places.

Cross Cutting Issues

My testimony would be incomplete if I did not mention several of my conceptual priorities for TSCA which do not fall neatly within one or another TSCA authority. The first of these is to link the various parts of TSCA more closely and to link TSCA authorities to the needs of other EPA programs. I intend to use the new chemical review process to identify categories of chemicals for review by the Existing Chemicals Task Force. I will be using health and environmental data gathered under Section 8 reporting information or Section 4 testing to facilitate review of structurally similar new chemicals. We are also working with EPA's Water, Air, Superfund and Solid Waste Offices to identify areas of coordination.

I also believe that we should be doing a much better job of getting public participation in our TSCA decisions and publicly stating our rationales for making decisions. We have just started putting our preliminary chemical assessment documents out for public comment, and we now publish quarterly reports for both new and existing chemical decisions. But I believe we could do much more in this regard. Partnerships with States and the EPA regions are particularly important as we move toward sharing data which is now coming in. In summary, I feel confident with the course I have set: to collect enough information to identify and categorize problems; to coordinate with other EPA programs and other Federal agencies to encourage action under appropriate authority; and when there is a void to fill it with action under TSCA.

I realize that this has been a great deal of information on TSCA. I have tried to stay away from a recital of achievements or numbers, but rather to give you a sense of TSCA for what it is: an emerging program. In some areas, such as the new chemical review program, we have developed considerable expertise. In other areas, we have yet to test the law's authority. As I look to the next year, I am enthusiastic about the amount to be accomplished. I will continue to welcome this Committee's views and suggestions on how to make TSCA implementation truly protective of health and the environment.

I thank the Committee for its time and attention, and I am ready to answer any questions you may have.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Honorable David Durenberger
Chairman, Subcommittee on
Toxic Substances and
Environmental Oversight
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed are our responses to questions 1 through 14 of your October 5, 1983 letter to me. These are the questions relating to implementation of the Toxic Substances Control Act. As discussed with your staff, our responses on the remaining questions, which relate to the implementation of the Federal Insecticide, Fungicide and Rodenticide Act, will take a bit longer to complete. We expect to forward those pesticide-related responses to you by November 24, 1983. I hope you find the enclosed responses adequate to explain our views on the issues raised in the Subcommittee's questions. Please do not hesitate to contact me if further questions arise.

Sincerely yours,

Don R. Clay
Acting Assistant Administrator
for Pesticides and
Toxic Substances

1. QUESTION: On January 27, 1981, EPA published in the FEDERAL REGISTER a policy statement that provided guidance to chemical companies planning to submit premanufacture notices. The policy statement concerned the types of data that EPA generally needs to conduct adequate premanufacture risk assessments. The policy statement emphasized flexibility in use of the testing guidance, and it stated that its use was voluntary. Can EPA document any demonstrable effect of this voluntary testing guidance on the amount of test data submitted in premanufacture notices received subsequent to the publication of the guidance? If a quantitative response to this question is not possible, what are your impressions about the effect of this policy, and on what sources of information are these impressions based?

RESPONSE: EPA cannot document any demonstrable effect of the testing guidance on the amount of test data received in premanufacture notices. Both the amount and the nature of data submitted with notices have remained fairly unchanged since January 1981, based on a review of EPA's records.

In recent months, the chemical industry has shown increased interest in performing additional tests to address EPA concerns which are raised during review of a premanufacture notice. We believe this results from our increased emphasis on obtaining data to resolve specific concerns and from our actions to control the use of certain new substances which we believe may present an unreasonable risk to health or the environment. Prompted by similar considerations, individual chemical manufacturers and importers have consulted with EPA before submitting a notice to determine what type of information would be most helpful to our review. The 1981 testing guidance has been useful in these discussions as a starting point for identifying acceptable methods for developing data.

2(a). QUESTION: You have testified that the Agency does not question or challenge an industry claim of confidentiality until and unless a citizen requests the information under the provisions of the Freedom of Information Act. What is the rationale for this policy?

RESPONSE: As a general rule, the Agency does not require companies to fully justify or "substantiate" claims of confidentiality unless the information has been requested under the Freedom of Information Act or if the Agency identifies some other reason to challenge a claim. There are a number of important reasons for this policy. The number of claims of confidentiality asserted by companies is very high with or without a substantiation requirement, especially for new chemicals. Evaluating the adequacy of substantiations is an extremely resource intensive activity, especially in light of the frequency of claims and the volume of information submitted under TSCA. Even when claim substantiations are evaluated, few have been determined to be unfounded under the broad provisions of section 14 of TSCA.

For nearly two years the Agency required companies submitting Premanufacture Notices (PMNs) to substantiate all claims of confidentiality. This requirement was withdrawn in July 1982 (47 Fed. Reg. 28969) because the

Agency determined that it was not significantly improving public accessibility to PMN information.

To alleviate some of the public information restrictions caused by requirements of section 14 of TSCA, the Agency has developed statistical means of producing aggregate data from some TSCA section 8 data bases. Procedures are already in place to release different industry totals for information submitted for the TSCA Inventory as well as the section 8(a) Preliminary Assessment Information and section 8(a) Asbestos Reporting Requirements rules.

2(b). QUESTION: Has there ever been an instance in which a company claimed confidential status for a health and safety study? If so, what was the Agency's response to the claim? To your knowledge are there any health and safety studies that are classified as confidential at this time?

RESPONSE: Claims of confidentiality have been asserted for information which the Agency believes to be health and safety studies. When EPA identifies a claim that seems to be contrary to the provisions of section 14(b), the Agency's initial response is to notify the submitter and request that the claim be withdrawn. If the claim is not withdrawn, the company is required to justify why the information should not be released to the public pursuant to section 14(b) of TSCA. Because TSCA allows companies to assert a claim of confidentiality for virtually all information submitted under the Act and requires the Agency to provide notice to companies before making public information for which a claim has been asserted, it is very likely that some health and safety studies are classified as confidential at any given instance. In addition, it should be noted that section 14(b) requires that studies or portions thereof that would disclose processing information or the portions of a mixture and that are claimed as confidential be treated in the same manner as any other information claimed confidential under section 14(a).

The greatest number of health and safety studies submitted under TSCA to date (over 4300) were provided in response to the section 8(d) Health and Safety Data Reporting Rule; approximately 40% of these studies were accompanied by some claim of confidentiality which the Agency is questioning.

3(a). QUESTION: There were press reports recently that EPA received notice that a particular chemical was found to cause bone cancer in test animals, but that both the name of the chemical and the name of the company submitting the information were claimed confidential. Did this, in fact, occur? If so, what steps, if any, has EPA taken to release the name of the chemical to persons who may be exposed to it?

RESPONSE: On June 17, 1983, the Office of Toxic Substances (OTS) received a section 8(e) substantial risk notice stating that preliminary findings from two ongoing long-term oral administration studies indicated that the tested chemical had induced a dose-dependent and significant number of bone tumors in rats. The submitting company claimed its name and the identity of the subject chemical to be "Confidential Business Information." Immediately upon receipt of the reported information, OTS staff contacted the submitter by phone to discuss the company's confidentiality claims for chemical identity. As a result of this discussion, the submitter, by letter, withdrew all claims of confidentiality for the identity of the chemical, thereby allowing the Agency to release the following chemical substance name to the public; ethylenediaminetetra (methylenephosphonic acid) or EDTMPA. It should be noted that, although the identity of another chemical that was being tested in combination with EDTMPA in one of the ongoing long term studies is still considered to be confidential, that chemical (Chemical X) does not appear, based on the submitted information, to have had any influence on the observed rat bone cancer induction by EDTMPA.

In response to the TSCA section 8(e) notice on EDTMPA, OTS staff prepared a "status report" containing a summary of the submitted information, an initial evaluation of the submitted information by OTS scientists, a summary of readily available production and use information on EDTMPA, and a description of OTS/EPA followup actions and activities designed to 1) gather further information on EDTMPA; 2) better evaluate the nature and extent of potential hazards/risks posed by exposure to EDTMPA; and 3) inform others about the preliminary results of the EDTMPA long-term studies. The following summarizes the OTS actions taken and activities initiated to date on EDTMPA:

- o The submitting company and other companies have been requested to provide EPA with additional toxicity and exposure information on EDTMPA;

- a Production/Exposure Profile (PEP) on EDTMPA has been prepared for OTS;

- a Chemical Hazard Information Profile (CHIP) on EDTMPA is now being prepared by OTS; and

- copies of the TSCA section 8(e) "status report" on EDTMPA were sent by OTS to other govenment agencies (National Institute for Occupational Safety and Health, Occupational Safety and Health Administration, Consumer Product Safety Commission, Food and Drug Administration) and to other EPA program offices and regional offices. A copy of the "status report" has been placed in EPA's public TSCA section 8(e) files.

Although in the case of the TSCA section 8(e) submission on EDTMPA the submitting company itself released the actual identity of the chemical substance of concern, EPA does have the statutory authority under section 14 of TSCA to publically release the identity of a chemical which has been claimed as confidential if the Agency determines, for example, that such action is necessary "to protect health or the environment against an unreasonable risk....."

3(b). QUESTION: In qualitative terms, how frequently does EPA recieve claims for confidentiality that mask the linkage between a possible toxic effect and the chemical that is involved?

RESPONSE: With regard to section 8(e) submissions, claims of confidentiality for the exact identity of a subject chemical are rare. EPA carefully reviews such claims with the objective of releasing adequate information about the identity of the subject chemical to permit those who may be exposed to it, and other manufacturers and/or processors of the chemical, to comprehend the significance of the "substantial risk" data to their own situtations. In cases where there appears to be a legitimate basis for such confidentiality claims, EPA requests submitting companies to provide non-confidential "generic" names for the chemicals of concern. It should be noted that many companies submit generic names even without EPA so requesting. In most cases, a generic name, although not exact, does provide sufficient information to those persons who manufacture, process, distribute, and/or use the chemical to take appropriate actions designed to reduce and/or eliminate risk of injury to health or the environment.

4. QUESTION: Does EPA consider such things as epidemiological studies, worker health screening surveys, summary worker medical records, and workplace ambient air monitoring records to be "health and safety studies" under section 14 of the TSCA, and therefore generally ineligible for "confidential" status? Or, alternatively, are companies allowed to claim studies such as these to be confidential?

RESPONSE: Pursuant to section 14(b) of TSCA, companies are allowed to claim health and safety studies, or portions thereof, as confidential if the companies can satisfy the Agency that release of the materials would reveal otherwise confidential chemical process information, the portion of a mixture comprised by any chemical in the mixture, or individual medical records that would be excludable from release because of privacy considerations. As generic groups, epidemiological studies, worker health screening surveys, summary worker medical records, workplace monitoring records, as well as other studies that measure occupational exposure to an effect from chemical substances or mixtures, would be considered health and safety studies for purposes of TSCA.

5. QUESTION: Though actual or potential exposure is as important as chemical toxicity in determining the risk presented by a chemical, section 4 test rules and negotiated agreements are aimed at toxicity testing only.

How does EPA get the exposure information it needs to support a risk assessment? Please give specific examples. Does EPA require companies to conduct monitoring studies, epidemiological studies, and medical screening surveys, as opposed to simply obtaining the results of studies already conducted? Would such studies, if required by EPA, provide useful information in some cases?

RESPONSE: Exposure information is obtained in several ways:

a) Section 8(a) authority to require chemical companies to submit reports. Example: section 8 Asbestos Information Reporting Rule.

b) section 8(d) requirement to submit existing health and safety studies, including industrial hygiene surveys and monitoring studies.

c) Contract support. Numerous examples include Versar exposure assessment on formaldehyde, MRI monitoring study on 1,3-butadiene.

d) Workplace data through Interagency Agreement with NIOSH. Current example: study of 4,4'-methylenedianiline.

In addition, EPA has included chemical fate testing in several proposed test rules. Such data are a critical component of analyzing certain types of exposure situations.

EPA has not as yet required chemical companies to conduct monitoring studies, epidemiological studies, and medical screening studies. We interpret section 4 to authorize such requirements. We intend to require these kinds of studies to be done in cases where it is useful for the companies, rather than the government, to conduct them. (The government may have access to sites or records that are not available to companies because of confidentiality of records and processes.)

6. QUESTION: Congress anticipated that EPA would adopt a categorical approach to development of significant new use rules (SNUR's). For example, Senator Magnuson, the Floor Manager stated:

> The requirement that manufacturing and processing notices be given for significant new uses of chemical substances is extremely important. As chemical substances frequently are not manufactured in large volumes for a large number of uses initially, the authority to require notification for these substances as uses mount or as volumes increase is extremely important.
>
> ...The Administrator is expected to promulgate rules concerning significant new uses by categories in order to avoid a multiplicity of rulemaking proceedings.

Nonetheless, according to EPA's July 1983 "Priorities and Progress" report, the Agency has adopted a "case-by-case" approach to following up on new chemical risks using significant new use rules (SNURs).

Given this policy direction of Congress, why is EPA using only a "case-by-case" follow up on new chemicals?

RESPONSE: EPA has recently begun to take steps to broaden the scope of followup activities in two major areas. First, we intend to issue a broadly framed section 8(a) reporting rule that will obtain risk-related information on categories of new chemicals as they grow in the marketplace. While this rule will not replace the need for additional SNURs, it will complement our SNUR rulemaking activities and play an important role in identifying future risks. Second, we are currently reviewing our experience in the PMN program with the objective of identifying categories of new chemicals that may warrant regulatory action. One of the regulatory options we are exploring is the use of categorical SNURs. We believe that such an approach is very desirable from a resource standpoint as well as from a risk control perspective.

Our past activities were limited to the "case-by-case" approach because (1) we did not have significant PMN review experience to identify chemicals that may have warranted regulatory action on a categorical basis, and (2) we believed it necessary to first gain experience in developing and issuing SNURs for individual chemicals before undertaking a categorical approach which is often more complicated than chemical-specific rulemakings. Now that we have gained sufficient experience in developing SNURs and have an adequate PMN review history to identify potential categories of concern we have begun to explore categorical approaches to regulation. We anticipate that categorical rules will raise many issues but also believe that the potential benefits will warrant pursuit of this approach.

Finally, EPA has made considerable progress in implementing a followup program for new chemical substances. Three significant new use rules covering five chemical substances have been proposed in the FEDERAL REGISTER and several others have cleared Agency review and will soon be published. We expect to exceed our projection of 10 SNURs per year and believe that the case-by-case followup program will continue to play an important role in our new chemical program.

7. QUESTION: Please describe the status of data sharing arrangements both with other EPA programs and other agencies that provide to these other regulatory entities TSCA data that have been claimed confidential by chemical companies.

RESPONSE: EPA presently has agreements with several other agencies to share confidential information submitted under TSCA. The Occupational Safety and Health Administration reviews information submitted under section 8 of TSCA. The Consumer Product Safety Commission reviews PMN notices and section 8 information for substances which might have consumer application. The Interagency Testing Committee, which includes members from the OSHA, CEQ, NIOSH, NIEHS, NSF, National Cancer Institute and Department of Commerce has access to confidential TSCA section 4 and 8 information for its work in designating chemicals as testing candidates. Access has also been provided to OMB, Congressional entities such as GAO and OTA, and to a number of congressional committees. The Office of Pesticides and Toxic Substances routinely shares TSCA confidential business information with members of other EPA program offices who have been cleared for access.

8. QUESTION: If EPA were provided, under TSCA, information relevant to a rulemaking proceeding, would EPA or another agency be able to use that information in support of the rulemaking? What procedural steps would have to be taken before such information could be used and what would be the effect on the schedule of the rulemaking?

RESPONSE: We assume that this question actually refers to use of EPA confidential business information (CBI) to support rulemaking. The information must be handled according to TSCA CBI procedures; however, these procedures are unlikely to affect rulemaking schedules. EPA has frequently used such information to support its rulemakings. For example, CBI submitted in PMNs was used to support EPA's risk assessments for the polymer and site-limited intermediate/low volume chemical exemptions under section 5(h)(4). Confidential information is also used routinely in significant new use rules and section 5(e) orders. In such cases, the information is described in the rule generically, so that CBI is not disclosed to the public. Additionally, the Agency can aggregate the data in such a way as to mask the underlying confidential elements. However, arriving at a proper aggregation can be very time consuming.

EPA has developed procedures for providing TSCA confidential information to other Federal agencies. Under these procedures, which have been issued by rule (40 CFR 2.306h and 2.209), the other agency must specify why and what it needs, and agree to comply with TSCA CBI procedures. Under such agreements, EPA has already shared TSCA CBI information with the Occupational Safety and Health Administration and the Consumer Product Safety Commission. We do not believe that complying with confidentiality procedures has had any effect on OSHA or CPSC rulemaking schedules.

TSCA section 14(a)(4) allows EPA to disclose confidential information in any proceedings under the Act, "except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceedings." EPA has not yet found it necessary to disclose any CBI under section 14(a)(4); however, it has developed procedures for disclosing information under this authority (40 CFR 2.306(i)). Under these procedures, EPA must determine that disclosure is necessary to the proceeding, and it must provide the person who submitted the information opportunity to comment. These procedures are expedited; therefore, EPA does not believe that they are likely to delay a rulemaking or other proceeding under TSCA.

9. QUESTION: TSCA contains broad authority in section 4 and 8 to obtain information related to chemical manufacture, marketing, transport, use and disposal. This authority could be used to support directly the information needs of other chemical regulatory programs. Is TSCA being used for this purpose? Please describe specifically the extent to which data gathered under TSCA has been used to support regulatory analyses under other EPA programs, as well as by the Occupational Safety and Health Administration and the Consumer Product Safety Commission. Are there instances in which TSCA information authorities were called upon to support a particular regulatory activity being undertaken by another office?

RESPONSE: To date, TSCA's information gathering authority under sections 4 and 8 has been used primarily to support TSCA regulatory goals, although the data generated will and does also support other Federal programs. For example, information concerning asbestos, which was obtained through section 8(a), has been made available to other EPA programs and to OSHA and CPSC. Where information was confidential, clearances were obtained to permit access by employees of other agencies. Health and safety studies on 4,4'-MDA obtained under the section 8(d) rule were requested by OSHA and made available to them. Other EPA offices and

Federal agencies also have access to other studies received under section 8(d). Information obtained under section 8(e) is routinely disseminated widely throughout the government. The section 8 inventory is routinely used by OSHA and other EPA program offices.

In developing section 8 reporting requirements, we try to consider other offices'/agencies' needs for data and incorporate those needs into the rule. For example, the Office of Solid Waste and Emergency Response is particularly interested in our efforts to develop a proposed rule to update the inventory and is working with us on drafting the rule.

10. QUESTION: Please describe the type, capability, and status of computer based chemical data systems developed by the Office of Toxic Substances (e.g., CSIN). Also, explain whether and how these systems are made available to other offices and to the public.

RESPONSE: In order to successfully implement TSCA, EPA's Office of Toxic Substances (OTS) has developed a number of chemical data systems to store TSCA submissions and to supplment commercially available bibliographic data bases. It is OTS' policy to make these systems or their information available to other offices and the public as long as the information has not been claimed as TSCA Confidential Business Information by the submitters. Where some of the information has been claimed as CBI, OTS has either prepared a sanitized system (e.g., Non-CBI CICIS system) which is available to other offices, or has released the data in aggregated form (e.g., section 8(a) Level A data).

The major OTS chemical data systems are as follows:

a. Chemicals in Commerce Information System (CICIS):

This system contains 1977 production range, manufacturing plant site and other data on 56,000 of the substances reported for the TSCA Chemical Substances Inventory. Substances where identities have been claimed as CBI are not included. Since some of the production and site data have been claimed as CBI, OTS currently maintains both a CBI CICIS and a Non-CBI CICIS which is available to the public. OTS also maintains the Master Inventory File (i.e., a compilation of automated and manual files) covering the specific identities of 61,000 substances including those with confidential identities. This file is used to support the determination of new substances for purposes of a premanufacture notification (PMN) under section 5 of TSCA.

b. UVCB System: This system contains chemical definitions for 1700 Inventory substances which are UVCBs (Unknown or Variable composition, Complex reaction products, and Biological materials). These definitions are searchable by key words. This system is non-CBI and is available to the public.

c. Scientific Parameters in Health and the Environment, Retrieval and Estimation (SPHERE): This system, which is currently under development, attempts to integrate a diverse range of OTS and other scientific data bases containing end-point data. Currently, two of these data bases, i.e., Aquatic Information Retrieval Data Base (AQUIRE) and Dermal Absorption Data Base (DERMAL) are available to OTS users and only DERMAL is available to the public. DERMAL contains data on study protocols, test organism details, summary results, dose results and detailed absorption, metabolism, distribution and excretion studies on 3699 studies for 655 substances. AQUIRE contains information on acute, chronic, bio-accumulative, and sublethal effects data on aquatic organisms. Four additional data bases are currently under development. Since SPHERE does not contain CBI data, these data bases, when developed, will be made available to other offices and the public.

d. Section 8(a) Level A Information System: This system contains production, manufacturer use and exposure data on over 300 substances included in the Preliminary Assessment Information Reporting Rule under section 8(a) and its amendments. The rules cover substances that have been selected by OTS or designated for testing consideration under section 4 of TSCA by the Interagency Testing Committee. As additional chemicals are added to the rule, the system will be updated accordingly.

Since the information is largely TSCA CBI, this system is not readily accessible by other offices. OTS, however, has agreed to share some of the data with CPSC and OSHA in accordance with TSCA CBI procedures. Furthermore, OTS has published data aggregation methodologies in the Federal Register so that aggregated data can be released to the public.

e. Section 8(a) Asbestos Information System: This system contains processing, use and exposure data on asbestos submitted under the section 8(a) Asbestos Reporting Rule. The data are TSCA CBI, and public access is restricted to aggregated data. OTS has agreed to share the data with OSHA in accordance with TSCA CBI procedures.

f. Technical Data Indexing System (TDIS): This system is an automated version of the PMN file, containing data or pointers to data extracted from PMNs received under section 5 of TSCA. Types of data include chemical identity, production volume estimates, use categories, with an index for the types of test data submitted for PMN substances. Since the information is largely confidential, the system is not made available to the public.

All of these systems provide certain standard outputs and can be accessed on-line. Specialized outputs can be prepared if needed. Updating is performed if and when new information is available.

The Chemical Substances Information Network (CSIN) is a sophisticated switching network that allows users without extensive knowledge of various individual data systems to obtain access to a variety of systems relevant to obtaining chemical data through a single access point. EPA is developing CSIN jointly with other agencies through the Interagency Toxic Substances Data Committee established under section 10(b) of TSCA. Over 400 individual data bases are now accessible through CSIN and over 400 individuals in 104 organizations have been trained in use of the network.

Another approach to making various chemical data systems more effectively available to OTS personnel has been our development of an OTS Information Architecture Notebook. This notebook provides conveniently organized information on the wide variety of data systems developed by or accessible to OTS staff. We would be glad to provide a copy of the notebook and a briefing on it to Subcommittee staff if you wish more datails on various OTS data systems.

11. QUESTION: Many states have active and growing programs to protect their citizens against chemical contamination of the environment. Please describe the measures that EPA takes to make available to a State chemical data obtained under TSCA that may be relevant to identifying or mitigating a chemical risk problem within the State. Please describe any statutory, administrative or other barriers that hinder information sharing with States.

RESPONSE: Over the past several years, OTS has made available to various state governments certain types of data obtained or developed under TSCA. While OTS will continue to share information with the states, there remains a major barrier to broader access by states to data obtained under TSCA. This barrier is the language of section 14 of the act. Section 14(a) specifies the limited situations and conditions under which TSCA confidential information can be disclosed to anyone other than EPA employees. Under that section EPA may disclose confidential information to the employees of other agencies and contractors and to specific sectors of the public if release is relevant to a proceeding under the Act or necessary to protect human health or the environment from unreasonable risk of injury. However, no provisions for state access to confidential information are included explicity or can very easily be read into the Act. Because of this statutory restriction and high protection and the high proportion of claims of confidentiality made for information submitted under TSCA, state access to TSCA information is often impeded. Therefore, OTS must constantly balance the need of the state governments for access to TSCA data with industry's need and the statutory requirements for the protection of CBI.

The following types of TSCA data can be shared with the states. Some of these data have been shared with the state governments in the past:

a. Section 8(d) Health and Safety Studies: Under a section 8(d) rule, OTS has collected over 4300 health and safety studies for nearly 300 substances. Most of this information is non-confidential and can be readily shared with the state governments. OTS has prepared microfiche copies of the submissions and is indexing the documents to facilitate retrieval. As additional chemicals (to date, principally substances nominated for testing by the Interagency Testing Committee) are added to the reporting rule, this collection of data will expand and would become a useful source of unpublished health and safety data.

b. Section 8(e) Notices: Under section 8(e) of TSCA, manufacturers, processors, and distributors of chemical substances are required to notify EPA of any substantial risk posed by substances to health or the environment. To date, OTS has received nearly 500 such notices and has been publishing in the TSCA Chemicals-in-Progress Bulletin the list of notices received. The Bulletin is sent to state governments. Copies of non-confidential section 8(e) notices can be provided upon request.

c. CHIP Reports. OTS regularly prepares Chemical Hazard Information Profiles (CHIPs) on selected chemicals as a preliminary step in its investigation of substances in commerce. These are reports on certain health and environment effects and exposure data on chemicals under review. The availability of these reports is routinely announced in the TSCA Chemicals-in-Progress Bulletin, which is sent to the state governments. There will be a subscription service for these reports, and state offices can take advantage of this service to obtain copies.

d. SPHERE Data: End-point data collected under the OTS SPHERE project (see answer to question 10) can be readily shared with the states.

e. Chemical Advisories (CA) and Advisory Circulars: OTS is developing CAs for selected chemicals and Advisory Circulars for certain new chemicals. These documents are intended to provided information on chemical risks and on control measures. They will be distributed to the states when available.

f. Section 4 Testing Data: Testing data developed under section 4 of TSCA would be a potential source for sharing with the states.

g. Sampling and Monitoring Data: OTS in the past has provided sampling and monitoring data to a number of states and will continue to do so in the future.

In addition to the above, OTS plans to share aggregated data with the states. Potential sharing would include data collected under the section 8(a) Preliminary Assessment Information Rule, and section 8(a) Asbestos Reporting Rule, and data collected for the TSCA Chemical Substances Inventory. The confidential nature of these data would not allow OTS to share them with the states except in aggregated or sanitized form. Unless the statute is changed, TSCA CBI data cannot be provided to the state governments.

12. QUESTION: Over the last two years EPA has moved to a section 4 policy of "voluntary testing agreements" with the manufacturers, claiming such negotiations provide more timely disposition of recommendations made by the ITC. What tools does EPA have to guarantee that negotiated agreements will be carried out, and how will those tools be used?

RESPONSE: It is important to note that while the testing under such negotiated testing agreements (NTAs) is indeed conducted voluntarily, the actual testing would have been required in any event. EPA has, in appropriate cases, accepted negotiated testing agreements because the data can be received significantly earlier. Every negotiated testing agreement contains a schedule for the start of testing and the submission of interim and final reports, as well as provisions for inspections and audits of testing facilities.

EPA monitors industry's performance through interim progress reports, which are usually required on a quarterly basis. EPA inspection and audit activities will verify the reported progress. If a test sponsor falls behind the schedule, EPA will determine the cause for delay and require the sponsor to take appropriate corrective action. If the sponsor fails to do so, EPA would inform the public of the sponsor's failure to live up to its agreement and could issue a test rule to require that testing be performed. We believe the combination of adverse publicity and threat of a rule will ensure that industry does not break its agreements. EPA's experience to date has shown that in no instance has a test sponsor refused to conduct agreed-upon testing, that in only one instance has a change by a sponsor in testing approach caused delays of concern to the Agency, and that a significant amount of testing data has been received in the last two years under approximately 5 negotiated testing agreements. In calendar year 1982, the Agency received over 100 toxicology studies under NTAs, while in 1983 over 200 more have already been received or are expected shortly. In the one instance in which a sponsor-initiated change in testing sequence was of concern to the Agency, EPA indicated its significant concern to the sponsor, who then followed EPA-requested program changes sufficient to obviate EPA's concerns.

13. QUESTION: Reports indicate that one of the first negotiated test rules, regarding chlorinated paraffins, has encountered delays in the testing schedule, and that disagreement has arisen between EPA and the manufacturers' testing consortium concerning data availability. Please describe the current situation, especially what steps EPA is taking to enforce the agreement as orginally written.

RESPONSE: The Chlorinated Paraffins Testing Consortium was organized and planned even prior to the ITC's listing of chlorinated paraffins for testing consideration. The international regulatory interactions have made the program unique. In addition, some of the problems associated with the chlorinated paraffins agreement were due to the fact that it was one of the first instances in which EPA accepted an ongoing industry testing program in lieu of requiring such testing by rule.

In the spring of 1983, EPA became aware of problems in the chlorinated paraffins testing program when the consortium failed to meet some of the test deadlines. Discussions with the Consortium revealed that various technical problems had been encountered in conducting several of the studies and that the consortium had made one fundamental change in the sequence of two tests that affected the schedule for several other tests. Because of difficulties the Consortium had concerning notification of the various member countries in the international consortium, EPA was not notified of either the problems or the schedule changes. At that point, EPA told the Consortium to initiate all test sequences by May 15, 1983, or it would initiate rulemaking. EPA also requested the Consortium to submit a revised schedule and monthly progress reports. The Consortium has complied with these requests.

EPA staff also conducted a laboratory inspection and study audit at the testing facility in May 1983 and found that some raw test data had existed at the contractor's test facility for several months, although they had not been written up into a report at the time of the audit or submitted to the test sponsors. Upon EPA's subsequent request for the data, the Consortium declined to provide the data, suggesting that it would not be appropriate to do so before it had a chance to review the data and assess their validity. On July 18, 1983, EPA sent a letter to the Consortium reminding it that its individual corporate members were subject to a statutory reporting obligation under TSCA section 8(e) to submit information which indicates a substantial risk of injury to health or the environment. Subsquently, the Consortium filed a section 8(e) notice on

September 8, 1983. The section 8(e) notice informed the Agency of significant environmental effects data which EPA is currently assessing.

Overall, EPA believes that the problems encountered with the negotiated testing program for the chlorinated paraffins have been reasonably resolved and have provided a valuable opportunity for the Agency to identify areas for strengthing its oversight of TSCA testing programs under negotiated agreements and test rules. Many of the problems were not unique to the negotiated approach and likely would have been encountered under a test rule had one been promulgated.

14. QUESTION: Testimony indicates that little activity has been taken under section 6 to date, apart from the regulation of PCBs specifically required by Congress. Though you testified that three or four chemicals are likely to be regulated soon under section 6, that is still a very low level of activity considering the comprehensive regulatory authority of section 6.

RESPONSE: One of the major problems with the existing chemicals program in the early years of TSCA was the absence of a coordinated process for identifying and characterizing potential risks, selecting those that warranted OTS control, and bringing specific issues to resolution. This problem was exacerbated by the priority and resources that were of necessity devoted to implementing statutorily mandated programs for premanufacture notice review, testing and PCBs. These programs are now in place and increasing emphasis is being given to existing chemical control. We established in FY 83 a process for identifying, assessing, and resolving existing chemical problems. The process is working well. Approximately 60 substances have been or now are under review in this program. About 1/4 have been dropped from active review; 2/3 have been targeted for further analysis and preliminary decisions within 12 months, and five have moved into regulatory development. We have initiated rulemaking on methylenebis (2-chloroaniline) and 4,4'-methylenedianiline, and will soon do so on 2-methyoxyethanol and 2-ethoxyethanol and their acetate esters. We also will soon be issuing a Chemical Advisory on used motor oil and will begin work on negotiated rulemaking on toluenediamines. Moreover, in FY 84 we will complete the list of three rulemakings begun in FY 82 on PCBs, and propose two rules on asbestos. We are currently conducting several extensive risk assessments which will add to our list of regulatory candidates (e.g., 1,3-butadiene, cutting fluids).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 8 1983

OFFICE OF
THE ADMINISTRATOR

Honorable David Durenberger
Chairman, Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This letter is in response to the questions submitted as a follow-up to the Subcommittee's July 27th hearing on toxic substances. Enclosed are the answers to questions 15 through 20 which deal with pesticides. The responses to questions 1 through 14 were submitted earlier under separate cover. Please do not hesitate to call us if we can be of further assistance in this or in other matters.

Sincerely yours,

Gregg Ward

Gregg Ward
Director
Office of Congressional Liaison

Attachment

Question 15

From FY 1980 to FY 1983, both the budget and the number of positions for the pesticides program have been significantly reduced. At the same time, according to a House Agriculture Subcommittee investigation, the registration-related activities have almost doubled. Can EPA continue to do so much more with so much less without a decline in the quality of individual performance or program decisions?

Answer

The Program has essentially reached the limit of its abilities to meet its workload successfully. However, for FY 1984 the Office of Pesticide Programs has received an increase of 40 FTE's which will help. These additional positions will: 1) increase the Program's strength in performing special reviews of suspect chemicals (14.4 FTE's); 2) enable the program to meet increased costs of registration activities resulting from litigation (13.9 FTE's); 3) enhance the program's information systems (4.2 FTE's); 4) permit development and implementation of a national monitoring plan (2.0 FTE's); 5) permit 10 additional lab audits (1.5 FTE's); and 6) increase the program's enforcement capabilities (4.0 FTE's).

While this increase in positions will strengthen the Program's ability to carry out its regulatory responsibilites, in general resource adequacy is best viewed in a relative sense, as it invariably involves a trade-off between money and time. With present funds EPA will be able to perform all required pesticide registration and other regulatory activities at a certain pace without sacrificing the quality of its pesticide decisions. With more money, the Program could probably do more at a faster pace. We recognize, however, that the Pesticide Program is competing with many other vital Federal projects for the taxpayer's dollar. We must consider all programs within a larger, national context, as the Administration strives to reduce the size of the Federal deficit. We are committed to making the Federal pesticide regulatory program as effective as possible, utilizing available resources, to best protect public health and the environment.

Question 16

As processing new individual registrations, exemptions, and other day-to-day activities consumes a greater share of program resources, what has happened to support for longer-term program activities such as environmental monitoring, updating and automating the data files, reregistration efforts, and special pesticide reviews?

As the demand for new individual registration decisions and other day-to-day activities goes up, the resources available for other, more long term activities go down. Support for and progress of these particular long-term activities is described below.

Answer

Environmental Monitoring

In accordance with section 20(b) of FIFRA, enacted in 1979, EPA is required to develop and periodically revise a national plan for monitoring pesticides. A plan implementing the original National Pesticide Monitoring Program was published in 1971 by the Federal Working Group on Pest Management (FWGPM). This plan was followed by EPA and other Federal agencies during the 1970's. The FWGPM was abolished in the late 1970's. In 1980, EPA completed a revised monitoring plan taking into account the new types of pesticides then (and now) in use. The new plan was never adopted, and the old plan lapsed in several areas due to conscious resource reductions in monitoring.

More recently, the House Committee on Agriculture has encouraged EPA to develop a new monitoring plan, and we have agreed to do so. As noted in the response to question 15, 2 FTE's will be devoted to this activity. The new plan is to be completed by October 1984 and in effect by January 1985. According to discussions with the Committee the plan should provide for maximum use of the work of other agencies, both State and Federal, by trying to obtain conformity and aggregation capability among these groups, rather than start a brand new, large Federal program. We believe that this approach makes sense and look forward to new plan.

Updating and Automating Data Files

As indicated in the response to question 15, the Program has received an additional 4.2 FTE's for FY 84 to enhance its information systems. With this increase the program will continue to upgrade its information management capabilities in an effort that started several years ago. By the end of this fiscal year, we will have microfiche of all the scientific data supporting pesticide registration, as well as reviews, audits, and other EPA characterizations of the data. Further, any subset of the collection will be easily retrievable through an automated index. This will allow every regulatory review to be done with the most complete data base possible. This document control system is being integrated with a product information system that will also be operational this fiscal year, and will enable our managers to analyze trends and statistics, to keep information like tolerances completely up-to-date, and to reach all the right producers when questions arise about particular ingredients, uses, or studies. Both these systems will also greatly improve the speed and quality of our responses to public requests for information. In addition, last month, a new system came on line that provides the public with computer access to label information on registered pesticides.

Reregistration Efforts and Special Pesticide Reviews

The Agency has pursued a deliberate long-term strategy for reviewing old chemicals:

- Dealing first with identified problems (Special Reviews);
- Obtaining new data on chemicals with inadequate data (Data Call-In)
- Curtailing uses, changing labels and/or reaffirming as appropriate previously approved uses of existing chemicals (Registration Standards).

Out of the approximately 600 groups of closely related pesticide active ingredients involved in the reregistration effort, 84 were selected for special reviews and 75 of these special reviews are complete. For FY 84, an additional 14.4 FTE's have been allotted to special reviews.

We have also systematically been calling in data to fill key data gaps, focusing first on those pesticides with the highest volume of use and use on food crops. To date the Agency has issued data call in notices for 167 pesticide chemicals and by 1985 will have requested testing on 95% of the pesticides used in the U.S. By 1988 we will have covered the remaining 10%.

In terms of Registration Standards we have issued over 68 standards so far and expect to issue standards for approximately half of the 600 chemical groups by the end of FY 1991. A list of standards issued is attached. (We estimate that standards will not be needed for the other half because they are out of production, will be voluntarily withdrawn or are natural substances not requiring review). The Agency is using a cluster approach to the development of standards so that chemicals with like uses are reviewed at the same time. Clusters have been ranked so that high volume and food use pesticides are addressed sooner rather than later.

This does not mean that all of the newly generated data will be assessed by the end of FY 1991 of course - that will take longer. But we do have a system and it is working. Of the 65 high use chemicals, almost all of them have been or are now being handled through either Special Review, Data Call-In or Registration Standards. A chart is attached displaying the Agency's progress in reviewing major pesticides. We are putting our resources and our attention on those chemicals that matter the most in terms of human exposure and health. A chart is attached showing the amount of resources in dollars and FTE's that EPA has devoted to Generic Chemical Reviews since 1979 (Generic Chemical Reviews include both Registration Standards and Special Reviews).

REGISTRATION STANDARDS COMPLETED

	Standard
FY-80	Metolachlor
	Chloroneb
	Terrazole
	Aspon
	4-Amino
	Fumarin
FY-81	Deet
	Dichlone
	Ethoxyquin
	6-12
	Dialifor
	Isopropalin
	Ammonium Sulfamate
	Bolstar
	Bifenox
	Chloramben
	Carboxin
	Naphthaleneacetic Acid
	Metalaxyl (Ridomil)
	Coumphas/Coral
	Phosalone
	Temephos
	Plantpin
	Warfarin
FY-82	Napthalene
	Aluminum Phosphide
	OBPA
	Hexazinone
	Methomyl
	Magnesium Phosphide
	Methoprene
	Terbacil
	MCPA (2-methyl-4-chlorophenoxyacetic)
	BKLFI-2
	Zinc Phosphide
	Endosulfan
	Dicrotophos
	Methamidophos
	Cycloheximide
	Chloropricin
	Glean
	Bromacil

	Standard
FY83---	Ethion
	Sulfur
	Boric Acid
	Methidathion
	Dioxathion
	Diallate
	Dimethoate
	Barium Metaborate
	Cryolite
	Ethoprop
	Terbufos
	Aliette
	Naled
	Monuron
	Monuron TCA
	Formetanate HCL
	Dicamba
	Diuron
	Butylate
	EPTC
	Atrazine
	Hypochlorite

OFFICE OF PESTICIDE PROGRAMS Old Chemical Screening

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                SIX HUNDRED ACTIVE INGREDIENTS

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TERATOGENICITY; REPRODUCTIVE EFFECTS;   OO  SEVERE NEUROTOXICITY; REDUCTIONS OF WILDLIFE;
BIG REDUCTIONS OF NON-TARGET SPECIES;   XO  REDUCTION IN ENDANGERED SPECIES; NO ANTIDOTE.
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      89                                        OTHERS
 SELECTED FOR                                  FOLLOWING
SPECIAL REVIEW                          RE-REGISTRATION PROCESS

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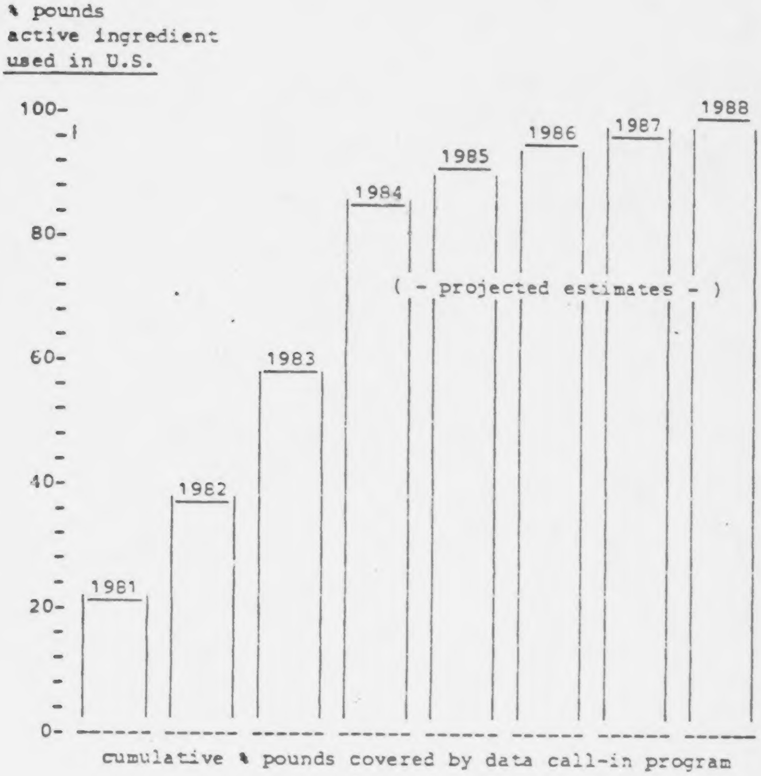
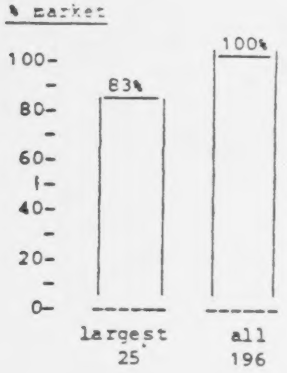
OFFICE OF PESTICIDE PROGRAMS Data Call-In Progress

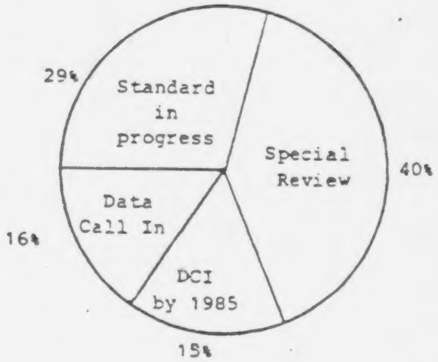


OFFICE OF PESTICIDE PROGRAMS Progress in Reviewing Major Pesticides

INSECTICIDES



For the largest 25 insecticides:



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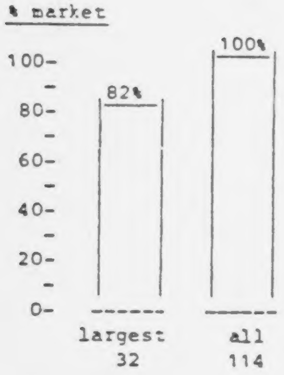

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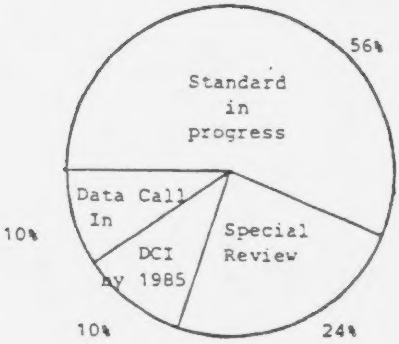

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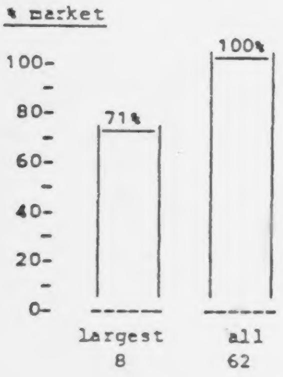

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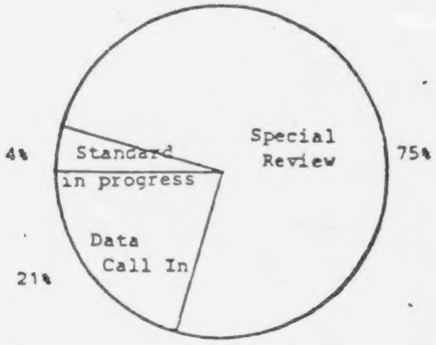

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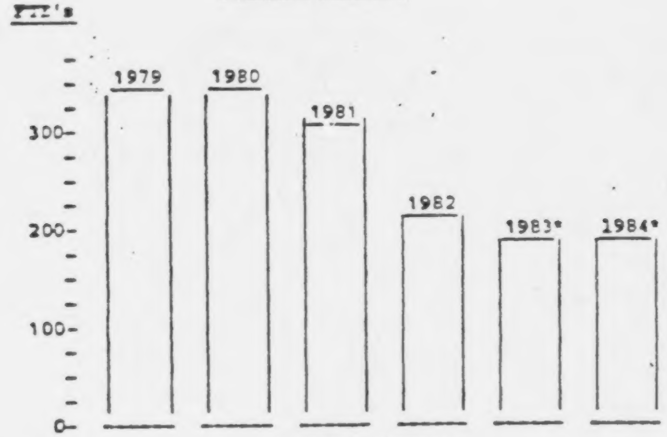
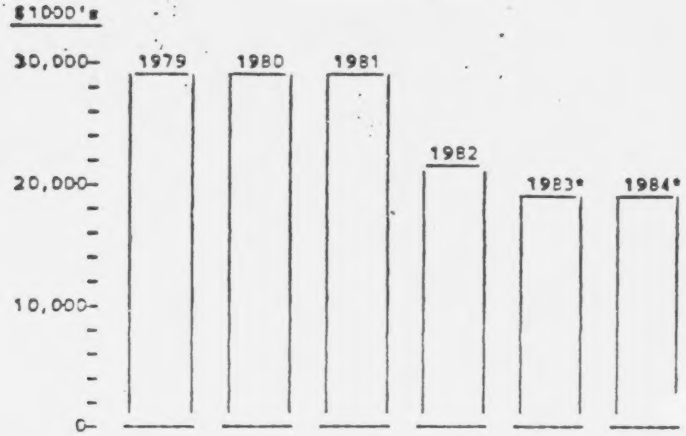


GENERIC REVIEWS



Question 17

Since January 1981, no new RPAR's have been issued, although the Agency has received data of the sort which arguably in the past would have triggered the RPAR designation. Why has EPA not issued any RPAR's in the last two years?

Answer

The RPAR program has achieved much of its original purpose by dealing with most of the older existing pesticide registrations that were identified in the mid 1970's as potentially posing unreasonable risks. The newer pesticide registrations were pre-screened for these risks when their newer, more complete data bases were submitted. Some additional RPAR candidates are soon expected to emerge from the ongoing Registration Standards Program, which is requiring registrants to generate new, more complete data on old chemicals.

Question 18

In order to respond to emergency pesticide situations or to meet the unique needs of minor crop uses, Congress allows EPA to grant temporary registrations for "special local needs" and "emergency exemptions" under sections 18 and 24 of FIFRA. In recent years the number of such registrations has dramatically increased.

Does this dramatic increase in registrations which require less complete data than the full set of section 3 requirements indicate a circumvention of the process by registrants?

An internal EPA audit of this program indicates that "emergencies" and "special local needs" often extend over many years and over many states. What is EPA doing to help get fully registered and approved pesticide products to meet the regional or national needs of our agricultural community?

Answer

As noted, EPA did conduct a thorough audit of its activities under sections 18 and 24(c) of the FIFRA. While we found generally that both these programs worked well to meet emergency and special local pest control needs, we did find some indication of overuse of the crisis provisions of the emergency exemption regulations, and some incidents in which special local needs registrations were being used to circumvent the section 3 registration process. A copy of the audit is attached. [1]

The Agency now plans a number of administrative actions to ensure that these processes are not abused. A special study group is examining the Section 18 regulations' "crisis exemption" provisions, which allow States to authorize emergency uses in advance of applying to EPA for approval, and it will redefine "emergency" to better reflect the intentions of Congress. We will soon be soliciting public comments on the Section 18 regulations, and needed changes will be made through the notice and comment rulemaking process. We plan to hold public hearings as part of this process. In the meantime, Administrator Ruckelshaus has pledged that the Agency will seek public comment on all emergency exemptions involving new chemicals, and if we decide to grant such requests, we will publish a justification in the Federal

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[1] The audit referred to has been retained in committee files.

Register. Also, the Agency is reiterating the purpose of Section 18 to the States, and in connection with this, has prepared background and policy documents to be distributed to new State pesticide officials. To prevent circumvention of Section 3 by Section 24(c) special local needs registrations, the Agency will be re-organizing and updating its files to show where "special local needs" are being simultaneously provided for in many States. The Agency will then effectively "require" registrants to apply for Section 3 registrations for these uses by issuing Section 3(c)(2)(B) letters requiring the necessary data. In addition, we are toughening up on our review of emergency exemption applications involving brand new chemicals not yet registered, so we can ensure that the program will not be used for early market entry instead of going through the full registration process.

Questions for Don Clay from Senator Baucus:

1. Because I also serve on the Small Business Committee, I would like to ask you about the steps that you are taking to address the needs of small business in the administration of the TSCA program. I know that the Agency has established an Office of TSCA Assistance and has begun a Small Business Ombudsman program. With that in mind, what specific steps are you taking to examine the impact of TSCA on small firms and to identify measures which can minimize these burdens in a way that does not unduly increase risks to society?

2. One of the persistent complaints of the small business community is the lack of a consistent approach to small business in the development and implementation of EPA regulations. Would it not be advantageous to develop a small business policy in the TSCA program that would seek to increase the understanding and compliance of small businesses with TSCA regulations, and also minimize administrative burdens for this group?

3. In testimony presented to this subcommittee last summer, emphasis was placed on two separate but related concerns. The first had to do with EPA's "low-volume" exemption policy under Section 5 of the Act, and exactly what threshold was being used to define it. The second was concerned with recognizing problems of small businesses in complying with TSCA, particularly the reporting and recordkeeping provisions.

--Has EPA developed a definition of small businesses under Section 8(a) of the Act? If so, what does this mean to small businesses in terms of complying with the law and regulations?

--What is the "low volume threshold" currently being considered by EPA for purposes of exempting certain chemicals form premanufacturer notification?

4. I am somewhat concerned about the mechanics of the new chemicals follow up process that EPA is developing. Once a substance has passed through the Pre-market Notification Process, it can be produced and distributed at will by the manufacturer. EPA does not as I understand it have records of which "PMN" chemicals actually are developed commercially.

Having cleared this first hurdle, what mechanisms does the Agency have recourse to in assuring compliance with the notification of "significant new use rules"? Doesn't this entire process essentially rely on voluntary industry compliance?

Does the Agency have an estimate as to how many new chemicals may be marketed which have not been reported under the "PMN" process? Has the Agency uncovered any specific incidences of this occurence and have any penalties been assessed?

5. I have been concerned for some time that EPA should conduct research into wood smoke emissions with an emphasis on health effects assessments. The Committee adopted an amendment mandating this work as part of the Clean Air Act package last year. As yet however Congress has failed to act on this, and the Agency has not instituted a wood smoke study on its own.

Has the toxics program come across any evidence showing that wood burning stoves may harbor trace amounts of dioxin from the wood combustion process?

--Is any work proceeding to substantiate this phenomenon?

6. In your testimony, you note that in a year or so implementation of TSCA will have reached a point where EPA may suggest legislative changes. In general terms could you suggest some areas in which the law could be improved?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Honorable Max Baucus
Member, Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Senator Baucus:

Thank you for your letter of August 17, 1983, with questions regarding the implementation of the Toxic Substances Control Act (TSCA). Below are the answers to your questions:

1. The TSCA Assistance Office (TAO) has promoted several activities to assist small businesses in understanding and complying with TSCA. The office sponsors a toll-free telephone service manned by information specialists to handle inquiries, and has a Field Consultancy Service whereby small companies can, at no expense, receive on-site assistance in preparing premanufacture notifications (PMNs) on their new chemicals. This service is being broadened to include assistance in complying with other sections of TSCA.

TAO staff maintain contact with small business committees of several trade associations to keep abreast of problems that small companies discover in trying to comply with TSCA, and bring these matters to the attention of OTS management. This activity has been supplemented with an industry liaison operation in which numerous small companies, both manufacturers and processors, were visited to hear first-hand their complaints and report them to the TAO director. Another program involves setting up visits to chemical facilities, large and small, for groups of OTS professionals who have had little or no industrial experience. The purpose here is to broaden the understanding on the part of the regulators for the industry they regulate. I am enclosing brochures that outline TAO's external communication function with all parties interested in TSCA.

2. As I am sure you know, the Environmental Protection Agency (EPA), is required to ensure that all regulations comply with the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Act requires EPA to establish efficient, flexible

regulatory procedures which have a minimal economic impact on small businesses. In so doing, the Agency must assess the likely burden of each regulatory action, and take steps to minimize the burden on small firms while still achieving its regulatory goals. I have explained in question one some of the activities in which the Office of Toxic Substances has operated in order to help small businesses comply with TSCA. On an Agency-wide basis, the Small Business Ombudsman is developing a policy for small business in the development and implementation of EPA regulations. This Agency-wide policy will also involve activities under TSCA. On March 4-6, 1984, EPA will sponsor its first conference on small business. EPA invites comments from all interested parties to further develop the Agency's policy in this area.

3a. As you know, TSCA section 8(a) requires EPA to define and exempt all small manufacturers and processors from most regulations promulgated under that section. To date, EPA has developed individual small business definitions (i.e., exemption standards) for each section 8(a) reporting and recordkeeping rule. Future section 8(a) rules will also contain small business exemption standards; these standards will either be generic in nature or specific to the individual section 8(a) rule, based on the type of chemical involved.

EPA will continue to develop exemption standards on a rule-by-rule basis for section 8(a) rules involving "new" chemical substances. We define new chemicals as substances that were not listed on the initial or revised TSCA Chemical Substance Inventories. The Agency will also develop small processors definitions on a rule-by-rule basis.

In addition, EPA is developing a set of generic exemption standards for manufacturers (including importers) of "existing" chemical substances. We define existing chemicals as substances that are already listed on the initial Inventory or in Cumulative Supplement II of the Inventory, plus chemicals that have completed the PMN process and whose manufacturer has sent EPA a commencement of manufacture notice. The final generic rule will contain two exemption standards, either of which will enable manufacturers of existing chemicals to qualify as "small" for purposes of future section 8(a) rules. We expect this rule to be published within the next few months.

As a result of the generic rule, most small manufacturers of existing chemical substances, particularly the very smallest firms, will not have to comply with future section 8(a) information gathering rules involving those substances. EPA estimates that approximately 62% of all manufacturing firms with total annual sales of less than $40 million will be exempted from such rules. In addition, approximately 36% of all manufacturing firms will be exempt.

3b. EPA is now considering limited PMN exemptions for chemicals produced at 1000 kg and 10,000 kg or less per year. In each case, the manufacturer would have to comply with certain exemption conditions (such as notifying EPA 21 days before manufacture). These exemptions, which would reduce the PMN burden for low-volume new chemicals, are likely to be particularly advantageous for small manufacturers. EPA's data indicate that small businesses produce a disproportionately large percentage of low-volume new chemicals.

4a. Strictly speaking, substances which have passed through the premanufacture notification process can be produced and distributed at will by the manufacturer. In practice, however, the industry has been following the November 7, 1980, Revised Interim Policy which calls for the submission of a notice of commencement of manufacture on or before the date when manufacture begins. The voluntary practice will become mandatory when the Final Rule for Premanufacture Notice Requirements and Review Procedures takes effect. We expect the Rule to take effect in October 1983.

4b. Enforcement of significant new use rules (SNURs) does not rely on voluntary industry compliance. A SNUR is a regulation and violators are subject to penalties under section 15 of TSCA. Other remedies are available to EPA under section 7 and 17 of TSCA such as seeking an injunction to restrain violations of a SNUR and the seizure of chemical substances manufactured or processed in violation of a SNUR.

4c. The Agency does not have an estimate of how many chemicals are marketed without having gone through the PMN process. Several cases are now undergoing review for possible assessment of penalties for manufacture of chemicals without a PMN and recently two companies were assessed substantial penalties.

5. The Agency is aware of data reported in the scientific literature that suggest a link between small amounts of polychlorinated dioxins and combustion in wood burning stoves. This problem is addressed in a draft Dioxin Strategy which is presently undergoing internal review prior to a release later this fall. This issue is presently being examined by our Air office to determine whether further, more detailed assessments are merited, relative to the other dioxin concerns before us.

6. With respect to legislative changes, at this time we do not know what if any areas of TSCA might warrant modification. As I mentioned in my testimony, some sections of TSCA have only recently been implemented. We need more time and experience with these programs in operation in order to properly evaluate them.

Sincerely yours,

Don R. Clay
Acting Assistant Administrator
for Pesticides
and Toxic Substances

Enclosures

TOXIC SUBSTANCES CONTROL ACT OVERSIGHT

FRIDAY, JULY 29, 1983

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON TOXIC SUBSTANCES AND
ENVIRONMENTAL OVERSIGHT,
Washington, D.C.

The subcommittee met, at 9:40 a.m., in room SD-406, Dirksen Senate Office Building, Hon. Dave Durenberger (chairman of the subcommittee) presiding.

Present: Senator Durenberger.

OPENING STATEMENT ON HON. DAVE DURENBERGER, U.S. SENATOR FROM THE STATE OF MINNESOTA

Senator DURENBERGER. The hearing will come to order.

This is the second day of hearings on the subject of toxic substances. As you know, yesterday's hearing was rescheduled until next Monday at 10 oclock so that the committee could continue markup of the Resource Conservation and Recovery Act.

We heard excellent testimony on Wednesday from several distinguished scientists and also from the EPA. It was useful testimony, but to a degree disturbing.

The toxic substances problem in this country is far from solved. Moreover, it appears that we need to know a good deal more about the toxic effects of the chemical substances to which we are exposed, alone or in combination, to be able to take effective action to minimize risk to health or the environment.

Mr. Clay of the EPA gave his assurance that his program is raising its sights, but he also indicated that discretionary activity usually must yield to nondiscretionary duties. He also indicated that claims of confidentiality of chemical data are not challenged and that these claims which are legion prohibit the sharing of information with the States and the public, which has the most at stake, of course.

So the subcommittee has, I think, begun the process of identifying some of the problems. In today's hearing I expect we will hear about others and I expect that we will begin to get some different perspectives.

Our first panel will be Mr. J. Dexter Peach, Director of the Resources, Community, and Economic Development Division of the U.S. General Accounting Office; and Dr. Michael Gough, Office of Technology Assessment, Washington, D.C.

If both of those gentlemen are ready, we will call you up now. Your statements, in full, will be made part of the record. I assume you will identify the people who are coming up with you.

We would ask you to summarize your statements in approximately 10 minutes.

Please proceed.

STATEMENT OF J. DEXTER PEACH, DIRECTOR, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY VIC REZENDES, GROUP DIRECTOR, AND RALPH DOMENICK, EVALUATOR-IN-CHARGE

Mr. PEACH. Mr. Chairman, I am J. Dexter Peach, the Director of the Resources, Community, and Economic Development Division. I have asked to join me at the table today two of the principal people that we have had working for some number of years on toxic issues and also on the pesticides issue which you asked us to briefly touch on today.

In our division, Mr. Vic Rezendes is the group director for the work that we are basically doing with respect to those EPA activities, and Mr. Ralph Domenick is the evaluator-in-charge of some major work that we have both done in the past and some we have currently ongoing with respect to the toxic substances issue.

I will briefly go through my statement. It is condensed to summarize the major work we have done over the last few years in the toxic substances area.

Basically we have had four reports on TSCA since its enactment in 1976. They have looked at EPA's efforts to implement the legislative requirements of the act, EPA's regulatory action on specific chemicals, and EPA's use of voluntary testing agreements. We briefly summarize each one of those.

The initial work we did concerning TSCA resulted in a report in October 1980 entitled "EPA Is Slow to Carry Out its Responsibilities to Control Harmful Chemicals." The objective of that work was to determine the status of EPA's efforts to implement the Toxic Substances Control Act and to identify major issues confronting EPA in implementing the major program requirements concerning the screening of new chemicals, and information reporting, testing, and control of existing chemicals. We concluded there was no clear sense of direction to guide the program; and because of organizational and staffing problems, EPA had made limited progress in identifying and controlling existing chemicals and in developing a program to control new chemicals.

Recommendations were directed toward screening new chemicals and called for EPA to develop a strategy to obtain needed information on new chemicals using all TSCA authorities and establish evaluation criteria for each decision point in the premanufacture notification review process.

Since this report was issued, the premanufacture notification review process has been evolving, and we are now conducting another review at the request and interest of this committee and also a House committee which I will discuss later on.

Now, since the initial report, we also issued reports on EPA's efforts under TSCA to look at two specific toxic substances: polychlorinated biphenyls, PCB's; and asbestos.

Section 6(e) of the act directed EPA to control the manufacture, processing, distribution, use, and disposal of PCB's. In a December 1981 report, we stated that EPA had made limited progress in implementing the legislative mandate to control PCB's, and EPA has little assurance that industry is complying with its regulation, and that EPA's enforcement program lacked overall direction and did not encourage quick compliance.

That report recommended specific actions by EPA to provide more effective use of the agency's limited enforcement resources and encourage greater compliance. These included issuing revised guidance to enforcement personnel, developing an information system for PCB enforcement, providing earlier notification of violations so that corrective actions can be speeded up, and reviewing and revising EPA's PCB penalty policy and its application to better encourage compliance.

EPA has made some changes and has indicated that it is in the process of making other changes in the PCB inspection and enforcement program and its penalty policy that will be consistent with the recommended actions.

On asbestos, we reported on EPA's efforts to address the potential health risks associated with asbestos-containing materials that were sprayed on walls and ceilings to fireproof, inmulate, soundproof, and decorate many schools that were built or renovated between 1946 and 1972.

Our report, "Asbestos in Schools: A Dilemma," stated that by requiring all schools to be inspected for asbestos and parents and employees to be notified if asbestos is present without specifying when asbestos is hazardous enough to warrant abatement actions, EPA has created a serious dilemma for school officials.

When schools are inspected as required and found to contain asbestos, the school officials are faced with the decision of what to do about the asbestos. Our review found that the lack of definitive Federal criteria has resulted in States and localities using different criteria in arriving at their decisions.

The report concluded that until EPA develops more specific criteria about when the asbestos poses a problem and what actions are most appropriate, school officials may continue to overreact and spend money needlessly or, more importantly, underreact and expose school occupants to hazardous asbestos conditions.

We did not make any recommendations in this report because EPA was doing more research on this issue and expected to validate what it believed to be a promising quantitative measure for assessing asbestos exposure and to issue guidance based on this measure.

This measure has since undergone validation tests, and it has been shown to be an unreliable indicator of asbestos exposure. In March of this year, EPA published a document, "Guidance for Controlling Friable Asbestos-Containing Materials in Buildings," that provides information on asbestos used in buildings and describes in qualitative terms the types of conditions under which the asbestos may pose a health risk and the kinds of actions, such as encapsulation or removal, that might be considered for reducing or eliminating such risks.

I might add that this kind of guidance probably still doesn't meet the test of being fairly definitive guidance of when you would know you had a problem that deserved some type of corrective action and, given the nature of the problem, what type of corrective action may be most appropriate in those circumstances. It provides kinds of information that can be applied more generally by the schools in deciding what to do about their situation.

Our most recent report entitled "EPA Implementation of Selected Aspects of the Toxic Substances Control Act" was issued on December 7, 1982 to the chairman of the Senate Committee on Environment and Public Works. He asked us to determine if EPA had the authority to use negotiated testing agreements with the chemical industry to obtain needed health and environmental effects tests for chemical substances in lieu of issuing administrative rules formally requiring such testing.

The report presented our assessment that the act does provide EPA with the authority to obtain necessary testing through negotiated agreements instead of administrative rulemaking. The report did not assess the appropriateness of EPA's use of negotiated test agreements in specific instances, but this is being addressed in our current work.

Currently we have two reviews underway dealing with TSCA. One is an assessment of EPA's new chemicals program and the other focuses on how EPA is using its various TSCA authorities to investigate and regulate existing chemicals.

Our work on EPA's new chemicals program addresses the major differences between the EPA program for assessing new chemicals and the program adopted by the European Economic Community, and the adequacy of EPA's efforts and approach to protect against unreasonable risks to health and environment from new chemical substances. For example, EPA relies on structural activity relationship analysis to screen new chemicals, whereas the European Community requires mandatory testing of new chemicals.

Our work on EPA's existing chemicals program addresses how EPA is using its various authorities under TSCA to develop adequate data on the effect of existing chemical substances on health and environment and to regulate chemical substances that present an unreasonable risk of injury to health and the environment, and major obstacles to effective TSCA implementation and the range of actions that could be undertaken to overcome these obstacles.

Two issues that will be addressed in this work are priority setting for EPA work on existing chemicals and the appropriateness of the manner in which EPA is using voluntary agreements with industry to test or control chemicals in lieu of requiring these actions through administrative rulemaking.

We hope to complete that work and issue those reports in January 1984.

I might add in this area, Mr. Chairman, that we have looked at the testimony that was presented by EPA's Acting Assistant Administrator for Pesticides and Toxic Substances, just the other day to this subcommittee. Based on our review, it does indicate that EPA is considering some potentially promising changes in its approach under TSCA. Some of these have to do with followup notification of chemicals that have gone through prenotification review, if and when their production volume would reach a specific volume; and using the new chemicals review process to identify categories of chemicals for review. These are areas we also are looking at in our current work. We are hopeful we will have some helpful recommendations to EPA in terms of things that can be done in this area to improve regulations.

Let me just briefly mention the work on FIFRA, the Federal Insecticide, Fungicide, and Rodenticide Act.

Since the early 1970's, we have issued 17 reports on FIFRA and EPA's efforts relative to it. For the most part, these reports have addressed one or more of the following:

First, the registration, control, and use of individual pesticides;

Second, EPA's policies and procedures for registering and reregistering pesticides and their effectiveness in protecting public health and the environment from unreasonable risks associated with pesticides and their use; and

Third, the effectiveness of EPA's efforts to enforce the requirement for pesticide registration and compliance with the conditions of individual pesticide registrations.

During the past 2 years, we have issued two reports on FIFRA: one on EPA's enforcement efforts and the other on pesticide applicator certification.

The report on "Stronger Enforcement Needed Against Misuse of Pesticides" was issued in October 1981. It concluded that although enforcement of Federal pesticide laws is a key factor in insuring that the public and the environment are not unnecessarily exposed to hazardous pesticides, EPA and the States do not always properly investigate cases and sometimes take questionable enforcement actions.

The report made a number of recommendations for improving the program, and EPA has taken actions consistent with our major recommendations. These actions included: Providing improved guidance and training for enforcement personnel; implementing needed improvement in recordkeeping and reporting systems; and strengthening coordination with the Food and Drug Administration and improving management controls over FDA referrals of pesticide misuse.

An issue of current concern is increases that occurred and are continuing to occur in special registrations; that is, registration of pesticides for special local needs for which there is no Federal registration. The report questioned whether through special registration the requirement for Federal registration was being circumvented.

In other words, it has to do with how much and how often they are being used and what scope or level of activity you are talking about in terms of allowing the use of chemicals that are federally registered.

The pesticide applicator certification and training program offers some recommendations on how EPA could have assurance that applicators, people applying pesticides, are appropriately certified in that application. It is basically a State-level function. EPA is required to assure that States have an adequate program in this area. We found, based on a limited review in two States, there could be some improvement to make sure people certified to apply pesticides were adequately trained and capable of safely applying pesticides.

We are currently not doing any work with respect to FIFRA at this time.

That completes my statement. I and my colleagues, who have a great deal of experience in this area, would be pleased to answer your questions. Thank you.

Senator DURENBERGER. Thank you, Mr. Peach.

Dr. Gough.

STATEMENT OF MICHAEL GOUGH, OFFICE OF TECHNOLOGY ASSESSMENT

Dr. GOUGH. Thank you, Mr. Chairman.

The premanufacture notice program is the U.S. Government's effort to identify toxic substances before they enter commerce, to impose controls when necessary, and thereby to reduce unreasonable risks to human health and the environment. The Toxic Substances Control Act requires that a PMN be submitted to the Environmental Protection Agency at least 90 days before a new chemical is manufactured or imported into the United States.

EPA reviews each PMN to determine whether the chemical described in the notice presents or may present an unreasonable risk to human health or the environment. When EPA does not conclude that an unreasonable risk may be associated with the substance described in a PMN, manufacture of the chemical can begin at the end of the 90-day period. In the event that EPA determines that the substance presents or may present an unreasonable risk, the agency can regulate its manufacture, processing, use or disposal.

At the request of the chairman of the Subcommittee on Commerce, Transportation and Tourism, U.S. House of Representatives, the Office of Technology Assessment examined the information content of PMN's. The first draft of the paper, "Information Content of Premanufacture Notices," was completed in December 1982, and it was reviewed by about 30 individuals and organizations, including trade associations, environmental organizations, a trade union, and the EPA. The paper was published and released in April 1983.[1]

OTA examined 740 PMN's to prepare the background paper: 670 of those were the total PMN's received during the first 2 years of the PMN program's operation from July 1979 through June 1981. The remaining 70 PMNs were those received in June 1982.

I will stray from my written testimony here to report on the increased workload in the PMN program. In the 9 months of October 1982 through June 1983, EPA received 753 PMN's, almost 100 more than it received in the first 2 years of the program's operation.

OTA examined each PMN for the presence or absence of 45 items of information. For convenience, those items are grouped into three categories. The first category is six items of basic information specified by TSCA. The second category is additional physical chemical data. The third is toxicity information.

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[1] Copies of the referred-to paper have been furnished to the committee.

The completeness of the reporting of the first category is easily measured by comparing each PMN to the items specified for submission on PMN's in TSCA. It is impossible to make such a comparison in the cases of physical-chemical and toxicity information because TSCA does not require specific information about those properties. To provide a standard reference for measuring physical-chemical and toxicity information, OTA compared the items of information submitted on PMN's to lists of physical-chemical and toxicity tests that were developed for premarket testing of chemicals by the countries of the European Economic Community. The EEC tests are called the "Premarketing Data" set or MPD.

OTA divided all the PMN's into subgroups in order to make comparisons. For instance, the letter requesting the OTA study asked whether more data were submitted on PMN's that described chemicals that have actually entered manufacture as compared to those that have not. Time does not permit me to discuss all of the analyses presented in the written statement, but to illustrate OTA's approach, I will discuss consumer chemical PMN's.

Chemicals intended for consumer use are of special interest because of the large number of people who may be exposed to them. Not only are there many consumers, but the chances for misuse probably increase with the number of users. Consumer-use items are purchased in retail outlets and may or may not be used according to directions. Labels and instructions may be lost, washed off, ignored, or not understood. A particularly striking example of such an occurrence was the mistaken use of a lemon-scented dishwashing detergent to flavor tea when plastic bottles of the product were mailed to consumers in 1982.

Some 14 percent, 105, of the PMN's examined by OTA described chemicals that according to the submitting companies were intended for consumer use. There were only small differences in the frequency of submission of physical-chemical data between PMN's that described consumer-use chemicals and all other PMN's. However, toxicologic data were more frequently reported on PMN's describing consumer products.

The more frequent submission of toxicity data fits with the idea that greater concern is attached to consumer-use products by the manufacturers. Because of the potentially large number of people exposed to these products, more information is desirable to make reasonable decisions about risk. Despite the more frequent reporting of toxicity information on the consumer-use PMN's, about 40 percent reported no toxicity data.

Once a chemical completes PMN review, it goes on the inventory of chemical substances and is no longer subject to regulation as a new chemical. No restrictions are imposed on the manufacture, processing, use, or disposal of substances on the inventory. Therefore, some of the chemicals designated for nonconsumer uses on PMN's may in time become consumer-use chemicals or be incorporated into products to which consumers may be exposed. The result is that consumers may use or be exposed to chemicals that were not reviewed as consumer-use chemicals. If that is the case, the percentage of consumer-use chemicals for which toxicity data are available to EPA, of course, decreases.

TSCA singled out chemicals that may cause cancer, mutations, or birth defects, the so-called chronic health effects, for special concern. Tests for the capacity to cause cancer or birth defects are expensive and time-consuming, and only tests for mutagenicity can be expected to be carried out on chemicals before manufacture.

Overall, 17 percent of PMN's reported mutagenicity data. As expected, the frequency of reporting of these data was higher for nonpolymers, which as a group are more hazardous, than for polymers. Surprisingly, however, only 17 percent of nonpolymer, high-production volume, consumer-use PMN's reported mutagenicity data.

The OTA background paper contains 24 tables and 9 figures. It is difficult to summarize findings reported there and at the same time respect the complexity of the data and the limitations inherent in a study that was restricted to an examination of the frequency of data submission. Nevertheless, some summary findings can be presented.

OTA's results place limits on possible answers to questions about how much information EPA has received on PMN's. The reporting of TSCA-specified items is high. Five of the six specified items—chemical identity, production volumes, uses for the chemical, numbers of workers likely to be exposed in their places of employment, and disposal methods—were reported on about 90 percent of all PMN's. The sixth specified item, information about byproducts generated in the manufacture of the chemical, was reported on about two-thirds of all PMN's.

Some 96 percent of all PMN's reported at least one item of non-TSCA-specified physical-chemical formation; 53 percent reported at least one toxicity test result.

Therefore, the majority of all PMN's contain every TSCA-specified item and at least one item of physical-chemical information, and about half report at least one item of toxicity information. Turned around, of course, the previous statement says that not all PMN's report even the TSCA-specified items, and almost half report not one item of toxicity information.

Furthermore, only 17 percent of PMN's have any test information about the likelihood of a substance causing cancer, birth defects, or mutations—three effects that were singled out for special concern in TSCA. Even fewer, about 10 percent, report any information from tests that estimate environmental effects.

Regardless of how the information about the frequency of submission of data is interpreted, immediate questions arise about whether the information available for a particular substance is appropriate and sufficient. Answering those questions would require an examination of EPA's decisionmaking process about some PMN's on a case-by-case basis. That study would be different from the one done by OTA and would involve a process similar, in some regards, to that used by EPA to review PMN's. A group of scientists would review the data on a group of PMN's, supplement that information with other information available from the scientific literature and experts, decide if EPA's decisions were appropriate, and ask whether additional information on the PMN would have made a difference in the decisions.

In the meantime, OTA's findings about some trends in reporting information on PMN's are encouraging. For instance, the generally higher frequency of reporting of toxicity data on substances that are more likely to be hazards is encouraging. At the same time, many PMN's contain no toxicity information, and that finding must cause reservations to be attached to any conclusions about whether the information now reported is adequate for the review of all new chemicals.

That concludes my statement.

Senator DURENBERGER. Thank you very much.

Let me start with a couple questions to you, Dr. Gough. Given the lack of submitted data with the premanufacture notice, can you tell us to what extent EPA relies on surrogate information, such as the structure activity review analysis?

Dr. GOUGH. In many cases, when EPA does not receive test data, it must rely on structural activity relationship analysis. In some cases I think that is entirely appropriate, when the chemical is closely related to a chemical that is in commerce and about which we know a great deal. In other cases, if it is really a novel chemical, reliance on SAR may be inappropriate.

I would like to emphasize our report did not go into the level of detail necessary to see if the use of SAR was appropriate or not appropriate in particular cases.

Senator DURENBERGER. In your testimony you stated that, in general, more data are submitted for consumer-use chemicals, but still approximately half—or I think you corrected that to 40 percent, as I recall—of these reported no toxicity data.

I wonder if you might elaborate a little more on that, perhaps give us a reason or explanation as to why that might be the case.

Dr. GOUGH. Yes. I think your question and my answer to it is going to illustrate a real problem in trying to summarize this report.

At the suggestion of Dr. Davies, who is on the next panel, and who was a reviewer on the first draft, I looked at consumer-use chemicals in different production volumes: Those expected to be made in less than 1,000 kilograms a year, those expected to be made between 1,000 and 10,000 kilograms a year, and those expected to be made in 10,000 kilograms per year. I also divided PMN's between polymers and nonpolymers. Polymers, as a group, are less hazardous.

It turned out, if we put the polymers aside, that there is a great deal of acute toxic information submitted on nonpolymer PMN's, such as skin irritation tests. As I recall, 70 percent of the nonpolymers have that kind of toxicity data, which to my mind is very satisfying. But the reverse side of that is that only 17 percent of PMN's for those chemicals contain any chronic health data, which is what TSCA was largely aimed at.

Senator DURENBERGER. Are those tests expensive, in that latter area? What is the reason why there is only 17 percent?

Dr. GOUGH. I don't know the reason. The simplest test, which is a test for the capacity to cause mutations in bacteria, is not expensive, on the order of $1,000 or $2,000. I don't think cost is the reason.

Senator **Durenberger**. Let me ask it differently. Were you surprised in some way to find this?

Dr. **Gough**. Yes, I was. In fact, when I did the analysis, I was very encouraged because of all the acute toxicity data. Then I was very surprised to find out there was so little mutagenicity data for those chemicals. But I don't know the reason.

Senator **Durenberger**. But it probably isn't financial then.

Dr. **Gough**. No, I don't think so. Possibly manufacturers are hesitant to run a single mutagenicity test because of the possibility of a "false positive" result. That is a real possibility, and manufacturers may want to wait to carry out these tests until more is known about them.

Senator **Durenberger**. Mr. Peach, one of the things that we have learned, I think, is EPA tends to rely heavily on the structure activity review to make up for general lack of data in premanufacture notices. We have just had that confirmed for us.

You indicated in your testimony that you have been looking at the European chemical program. To what degree are European officials similarly willing to rely on SAR, as the EPA seems to have been?

Mr. **Peach**. I will ask Mr. Domenick to respond because he was just in Europe on that assignment recently and met directly with a number of the European officials in a number of countries. So he is in a good position with first-hand information.

Senator **Durenberger**. If you want to, if you have just returned and have other information you want to share with us, feel free to do so, other than directly in response to that question.

Mr. **Domenick**. I will preface my comments by saying that the people we met with in Europe included officials from several European governments, officials from the EEC Commission, officials from the Organization for Economic and Cooperative Development, as well as representatives from the industry trade associations in several European countries.

The European countries have chosen to go with a mandatory testing requirement as part of their notification process. So it wasn't surprising in terms of the views that were expressed about structural analysis. For the most part, they can be summarized as follows:

Their views expressed to us were that structural analysis is not a viable substitute for testing. They feel that it could be a useful tool if used in conjunction with testing. However, they also said that they believe the structural analysis needs to be further developed and that its capabilities need to be further tested and validated.

That is their perspective on structural analysis. There is not a lot of reliance on it as the primary source for assessing the new chemicals coming into the market.

Senator **Durenberger**. Do you have any other observations you want to share with us on the general subject that weren't included in Mr. Peach's statement, particularly as it relates to comparisons to what the European Community is doing?

Mr. **Peach**. I would add one point on the structure activity analysis. It will be interesting to see how it plays out as some of these chemicals are introduced in other locations in the world as well as in the United States. As more testing data becomes available better comparisons to SAR can be made.

Mr. DOMENICK. It should be pointed out that the European system is quite new in the sense that there haven't been very many new chemicals that have gone through that process. So it remains to be seen exactly how it is going to work out. But there is the potential that U.S.-manufactured chemical substances that go through the U.S. PMN's process, to the extent they would be marketed in Europe, would have to go through the European system and would have to be tested before they could be marketed in Europe. We could have a situation where U.S.-manufactured chemicals are tested for the European market but not for the U.S. market.

Senator DURENBERGER. Dr. Gough.

Dr. GOUGH. A couple of observations. I want to say again, to emphasize, that I think in some cases the SAR is completely appropriate. One of the examples that came up and was offered repeatedly in the review of the first draft of the OTA paper was that if a polymer is simply made longer, and we have a lot of experience with this shorter polymer, it doesn't seem to me to be necessary to submit any additional data about that polymer on a PMN.

The second point: One of the things I think we are either going to take advantage of now and capitalize on, or lose forever, is that the people who should know the most about structural activity analysis are the people in EPA. I mean, they are the ones who every day are using it to make decisions. I think that activity should be looked upon as a research resource for us, to somehow keep track of the decisions they make, keep track of how they make them, and somehow decide how good the decisions are.

Currently I think EPA is overburdened, and they can't do that.

Mr. DOMENICK. One thing we would point out is that in the European market, polymers are exempt from the notification process. Within the U.S. market, EPA is proposing to exempt most polymers from the notification process.

So we wouldn't disagree with the fact that, perhaps, polymers are something that the structural analysis could be used to make that kind of assessment.

Senator DURENBERGER. Let me follow up on a question to you, Dr. Gough. What does EPA do with a PMN for which no data are submitted and there is no good analog data?

Dr. GOUGH. If EPA comes to the conclusion that it may present an unreasonable risk, it can write a 5(e) order requiring that the submitter produce more information and delay the manufacture of the chemical until those data are submitted. They can either do that by order or do it by calling up the manufacturer informally and saying that we have some serious concerns, and that they can work out an agreement to suspend the review period while the submitter produces those data.

I think, in all cases so far either the data have been produced by the company or the company has withdrawn the PMN.

Mr. PEACH. I might add, just as a verification of what he was saying, that from our review, it has been very limited. There might have been a case or two where orders were issued. But generally, when EPA begins to express some reservations about the adequacy of information on a certain chemical, PMN is withdrawn by the submitters.

Senator DURENBERGER. What I am trying to get at here is I am curious to know how EPA can get to the decision about a threshold of risk without adequate data. Maybe we could wait and ask Marcia Williams later on. But do either of you have any observations on that subject?

Mr. DOMENICK. In assessing risk, there are really two parts to the equation. One is the toxicity of the substance itself. The other is the condition of use in terms of what exposure there is to people and the environment.

I don't think it is unreasonable to say that a lot of the chemicals coming in are for uses that EPA is looking at and saying that even if they were toxic, the exposure situation is such that it wouldn't present a great risk. So a lot of the information we are talking about not being there is related to toxicity, whereas a lot of times the estimate of risk can be based primarily on the exposure side.

Mr. PEACH. One of the issues we are looking at, that deals very much with that, is how you measure this idea of what the toxicity is against information on level of production and the actual use being made of the chemicals. Judgment's are being made on estimates of use and production. An important question is how to follow up on new chemicals to find out what changes have occurred and how those changes would impact on your equation of risk-benefit.

Senator DURENBERGER. Let me ask you, Mr. Peach, GAO has reported on a variety of shortcomings it sees in both the pesticides and toxic chemicals programs. Can you add any information as to what might explain the implementation problems that these programs have encountered?

Mr. PEACH. For one thing, I wouldn't want to downgrade the difficulty of the task EPA was given when they had to move into TSCA, because you had the question of both the existing chemicals already there and then setting up a process to deal with new chemicals. So there was a process of beginning to get an inventory of what are the existing chemicals we start with as a base line, and that presents some problems.

I think another general observation is that as it started, TSCA was a little bit of a poor relation in terms of how it fit into the EPA scheme of things. There was a lot of emphasis on the air pollution, water pollution programs, and other areas. Then a new program comes in, such as TSCA, which is supposed to fill gaps of things that aren't being regulated under other laws. And then trying to figure out how you are going to apply or deal with that particular law under that circumstance.

TSCA also required, unlike other laws, that EPA balance the risk and benefit in its decisions on these chemicals. So that was another thing they had to factor into their equation; that is, making judgments about how they would balance the risk and benefit.

These things taken together probably contributed to the slowness in the program. Also, there were probably resource limitations to a degree, as has been mentioned.

In some areas EPA established processes for carrying out various TSCA requirements without going back and evaluating how those processes were working and taking corrective actions where needed. I think those are several kinds of factors that all taken together contributed to the problems that we reported.

Dr. **Gough**. I would like to return for a moment to the question you asked me just a while ago about how does EPA make a decision about whether to require more information or not to require more information.

The answer to that question depends on where you sit. Of the people who reviewed the first draft of the OTA background paper, the chemical industry, in general was quite pleased with the EPA's efforts and commented favorably upon the judgment exercised by EPA officials in making decisions. Environmentalists, and indeed some of the people at EPA itself, instead of talking about professional judgment, talked about swallowing uncertainty. I think that both of those terms refer to the same thing, which is what you are asking me about. Sometimes there are fewer data than some people would like to see, and yet the agency has to make a decision on the basis of that limited data or ask for more data.

Senator **Durenberger**. Let me ask you both a question. I have the impression there is a lot of case-by-case analysis in this program for both testing chemicals and for new chemical followup. Would regulating or evaluating categories of chemicals in some way make the program more efficient?

Dr. **Gough**. Yes; I think so. I think the categories should be drawn with care. But I believe that if additional testing requirements or additional information requirements were made on some categories of chemicals, it would make a great deal of sense.

Returning to what EPA has done on other things or is proposing to do on other things, they are negotiating exemption of some chemicals from PMN reporting requirements. Polymers, low production chemicals, and chemicals made and used on one site are being considered for exemption. It seems to me that, by the same logic, EPA can say that it is going to require more information for some chemicals.

Senator **Durenberger**. Again let me ask the question I asked before. Do you know any reason why they have not moved any more in the direction of the categorical approach on the side we are talking about here in terms of testing new chemicals or chemical followup?

Dr. **Gough**. Yes. In informal conversations with people at EPA, they are worried they will be hit with a lawsuit. And if the law were written differently, they might proceed more quickly.

Mr. **Peach**. Likewise, the idea of regulating by category should be looked at very carefully as to potential because you are dealing with 60,000 chemicals out there in the TSCA existing chemicals inventory. In addition, you have large numbers of new chemicals being introduced. So that raises questions with resources. Is there a way we can divide the many chemicals and what is the most effective way to take a look at these?

In our ongoing work, we are looking at the idea of not only the question of the test data in terms of toxicity but also the question of looking at categories in terms of use and production levels. We think you have to balance off the question of toxicity and exposure as part of the risk-benefit equation.

We think you can look at categories in that type of area. Because of some of the concerns, just as he mentioned legal or other kinds of questions, I think it does have to be looked at very carefully, though, in deciding how you establish categories and how you come up with reasonable defenses for why you are approaching it the way you aree It is not simple to define.

Senator **Durenberger**. Thank you, gentlemen, very much. You have been very helpful. I am sure we will be able to call on both of you again.

Our next panel is Mr. Jeremiah J. Kenney, Jr., Union Carbide Corp.; and Dr. J. Clarence Davies, the Conservation Foundation, Washington, D.C.

Gentlemen, we welcome you both.

I have had a chance to read your testimony. It will be made part of the record in full. You may proceed to summarize it or proceed in whatever appropriate fashion and limit your remarks to 10 minutes, please. We would appreciate it.

STATEMENT OF J. CLARENCE DAVIES, THE CONSERVATION FOUNDATION

Dr. **Davies**. Let me read portions of my testimony because it does summarize what I would like to say.

I appreciate being given the opportunity to appear before you to discuss TSCA. I was responsible in 1970 for the original draft of what later became TSCA. I have followed closely the implementation of the act since its passage in 1976.

TSCA can be and should be one of the most important environmental laws on the books. Although it has sometimes been referred to as a "gap-filler," designed to supplement the other environmental statutes, this description understates the intent and potential of the act.

If TSCA is not being adequately implemented, and it is not, then the whole range of institutional and legal mechanisms we have established to protect the public from unreasonable risks from chemicals is flawed and vulnerable.

TSCA has three basic purposes. First, it is designed to obtain the information necessary to determine the degree of risk posed by particular chemicals or groups of chemicals. This is the purpose of section 4 of the act, which authorizes EPA to require testing of particular chemicals; of the various authorities in section 8, which allow EPA to obtain relevant information from chemical manufacturers and processors; and of some parts of section 5, the section which relates to new chemicals.

No other Federal health or safety statute contains as strong or as comprehensive a set of authorities for obtaining information about risk, and such information is essential for intelligent and balanced regulatory decisions.

The second purpose of TSCA is to prevent unreasonable risks from occurring. This is the rationale for section 5 of the act. Although we have applied a preventive approach to particular kinds of chemicals, notably drugs and pesticides, TSCA is the only general environmental statute that allows the Government to deal with problems before people are hurt and before industry has made a major economic investment.

TSCA's authorities relating to new chemicals are the major hope we have of making real long-term progress in controlling unreasonable risks. If these authorities are not adequately implemented, we will constantly face new problems, and the toxic-substance-of-the-month syndrome will continue indefinitely.

The third purpose that TSCA serves is to deal with existing unreasonable risks. The provisions for doing this are contained in section 6. Although the Clean Air Act, the Clean Water Act, and other laws are appropriate for dealing with many types of pollution problems, they are increasingly cumbersome and inappropriate for dealing with the new generation of toxic pollutants.

This new generation of pollutants is not limited to one particular medium or one particular use but, like asbestos and PCB's, is found in all segments of the environment and is readily transferable, both through natural processes and human actions, from one segment to another. TSCA is uniquely suited to deal with this kind of problem.

The reality of TSCA implementation has not matched the act's potential. EPA is not getting the information needed about existing chemicals, it is not adequately reviewing new chemicals, and it has done very little to regulate the risks that already exist. Let me try to describe some of the implementation problems and suggest in broad terms what might be done to solve them.

Let me skip over the discussion of section 4 of the act, which deals with testing. I think perhaps we can get to that in Q&A. Suffice it to say that no section 4 testing rules have been issued since the act's passage.

The most important shortcoming in TSCA implementation is the inadequacy of the information submitted in the premanufacturing notifications for new chemicals. The purpose of the premanufacturing notification is to allow EPA to make a "reasoned evaluation of the health and environmental effects" of a new chemical. On a large number of the most important new chemicals, EPA is not getting the information it needs to make such an evaluation. It is failing to meet its responsibility to see that new problems are not created as fast as the old ones are solved.

EPA and the chemical industry have offered two kinds of defenses of the existing system for reviewing new chemicals. The first is that given the volume of the chemical or its use, or the fact that it might be a polymer, the test data are not necessary. You have heard the testimony from Dr. Gough this morning. Eighty-three percent of the chemicals which are not polymers, are high-volume chemicals, and are used by consumers, 83 percent of those do not have chronic test data. What this means is the great majority of the notifications for the chemicals most likely to create unreasonable risks contained no information about the risks which are of most concern.

I also have some concern, and although there is no way to judge the seriousness of the problem, about the fact that 38 percent of the chemicals, of the PMN's submitted, did not contain the data that they are required to contain by law. I find this somewhat surprising and shocking. The law requires that data to be there. Now, how important that is from the standpoint of public health and safety, as I say, there is no way of knowing. But I think that was one of the more surprising findings of the OTA study.

The other defense that has been given for the lack of data on PMN's is the so-called structure activity relationship approach. You discussed that earlier this morning. There are two problems with this approach. One of the things did come out in the colloquy with the GAO; namely, there is considerable doubt on the part of people who are experts in the matter as to whether structure activity relationship analysis is a valid way to determine the risk of chemicals. The other problem is the approach taken by EPA puts the burden on the agency to go do a lot of analysis itself and collect at least some data on the PMN's, whereas at least my reading of the law makes it very clear that the burden is on the manufacturer to provide the data needed by the agency to make those kinds of evaluations. So, in effect, EPA has assumed part of the burden which in fact should be borne by the industry.

There are several ways in which adequate information on new chemicals could be assured. The Europeans have adopted the most direct approach, which is simply to list a set of tests which must be performed for each new chemical unless there are persuasive scientific reasons for not doing a particular test. Because of various differences between the European legislation and TSCA, the European approach should not be directly adopted here, although I think it does provide some important lessons.

A combination of testing guidelines enforced through section 5(e) of TSCA, modification of the wording of section 5(e) which allows EPA to require more data under certain conditions, and exemptions for categories of low-risk chemicals would provide a workable system for obtaining data on the effects of a chemical. Alternatively, and I understand this is under debate now in EPA, EPA could designate categories of potentially high-risk chemicals and promulgate a set of data requirements for those categories.

If that is in fact the route that the agency chooses to go, obviously a lot will depend on how broad the categories are, how long it takes them to get those out, and what kinds of testing are required and are they in fact required or just suggested, and what does the enforcement look like. There are a lot of questions that need to be answered.

Under section 6 of the act, aside from regulating PCB's, which was required by the statute, almost no actions of consequence have been taken to regulate existing chemical risks. Aerosol uses of CFC's, roadside dumping of dioxin, and a reporting rule for asbestos in schools are the only other actions which have been taken.

I was encouraged by Don Clay's testimony here Wednesday to the effect that EPA would take section 6 action for some uses of asbestos. I think that is a long overdue step.

The underlying reason section 6 has not been used more often is that EPA really has not developed a coherent strategy for dealing with the toxic substances problem. It has not faced up to the fact that dealing with toxics under the older medium-specific laws all too often results in the problem simply being shifted from one part of the environment to another. If a coherent strategy were developed, I think that TSCA section 6 logically should be a key part of it. However, there is no indication that the agency is even thinking along these lines, much less taking any action.

There has been a basic acceptance of the need for TSCA. The chemical industry, to its credit, has accepted that there is a governmental and public role in examining new chemicals and in insuring that chemicals now on the market do not pose unreasonable risks. There is a consensus that the basic purposes and framework of TSCA are valid and necessary.

There is not a consensus about how the act has been implemented. However, in the face of no testing rules, no significant new use rules, almost no section 6 rules, and blatantly inadequate information submitted on new chemicals, it seems to me obvious that TSCA implementation has been less than satisfactory. Neither the Congress nor the American public are getting the information and the protection that they expected when the act was passed.

The language of the statute is generally flexible, although many of its procedural aspects are unnecessarily cumbersome. At least in theory, adequate authority exists in the act to undertake almost any action necessary to deal with chemical risks. But if these authorities have not been exercised by two administrations over a period of 7 years, something needs to change. The most direct and effective way for Congress to get what it thought it was getting in 1976 is to amend the statute to make the congressional intent crystal clear and to remove some of the procedural difficulties that the act contains.

It is vitally important that TSCA be adequately implemented. The problem of toxic chemicals is serious, and we are still in the early stages of discovering its true dimensions. TSCA is potentially the best tool we have for dealing with the problems and for getting the information to separate unreasonable risks from tolerable ones. Whether its potential will be realized depends heavily on the actions of your committee.

Thank you.

Senator **Durenberger**. Thank you very much.

Mr. Kenney.

STATEMENT OF JEREMIAH J. KENNEY, JR., DIRECTOR, FEDERAL AFFAIRS, UNION CARBIDE CORP.

Mr. **Kenney**. Thank you, Mr. Chairman. I will summarize my statement, too.

It is a pleasure to respond to the invitation of the committee to discuss the provisions of this statute and to provide some observations on how it is working.

The statute, as you will recall, and have heard, was before Congress a total of 6 years. It passed the Senate three times, passed the House of Representatives three times. It went through conference once before it was finally enacted into law. To many it was a frustrating process. But it is a process that had its good points, because the concepts and the language of the act were intensively considered and reviewed three times by the Senate Commerce Committee, three times by the House Committee on Energy and Commerce, as it is now called, and by the subcommittees of both committees, and by a conference committee. Its provisions were refined over 6 years by many talented Members of the House and Senate, by the efforts of many skilled persons on congressional staffs, and by a lot of input from the administration, environmental groups, and business organizations. In the end the bill had a broad spectrum of informed support across all areas of our society with an interest in its provisions.

There are several characteristics of the act that deserve special mention in light of this legislative history. You have heard it is a broad statute. Its provisions are basically applicable to all matter. The authority conferred by the statute is as deep as it is wide. The remedies available to EPA are enormously broad. In the ultimate, it can do almost anything from slapping a company on the wrist to putting it out of business, if the court approves.

There are two other aspects that flow from this situation. First, there are significant elements of due process woven into the statute in response to constitutional requirements. Second, the statute is designed as a gap-filling, back-stop measure intended to be invoked when other measures are ineffective.

It is a complex statute, but so are the problems it must cope with. But to say that the law is complex is not to say it is disorderly or incomplete or inchoate. There is sound logic to its provisions. It may be worth noting that through all of its years of consideration no Members of Congress stepped up to offer an easier or simpler way. Neither were any of the rest of us able to find that kind of a solution.

The statute provides for environmental purposes what might be called a defense in depth. Some of my colleagues in industry might view this as double or triple jeopardy. A new chemical substance can make its way through the premanufacturing notice procedure only to be faced later with testing requirements under section 4, new use restrictions, and potential extinction under sections 6 and 7. Except for the premanufacturing notice, any existing chemical can face the same gamut of regulation and control. No chemical substance is ever home free under the statute. This is the way it ought to be.

The statute is, of course, flexible. It grants wide areas of discretion. The discretion is seldom absolute because the committees which drafted the statute spent a lot of time and effort crafting careful guidelines and criteria. Nevertheless, the Congress determined, and wisely in my view, that the breadth, complexity and variety of problems likely to arise under the statute could only be dealt with by conferring a great deal of discretion to the informed expertise of the agency.

This is well illustrated by the problems dealing with premanufacturing notices for new chemicals.

There are several points I would like to make in this respect, some of which have been made earlier, so I will be brief on them.

Most new chemicals do not involve new chemistry. They are minor modifications of existing chemicals. Most chemical manufacturers operate within relatively narrow bands of chemistry, in areas where they have expertise and experience. These new chemical substances then in many respects do not present novel environmental problems, and their effects can readily be predicted in many cases from what is already known about similar and closely related substances. There is little to gain in testing for knowledge that is already on hand.

Many new chemicals cannot stand the costs of extensive testing, and certainly not before their producers know whether or not they will ever succeed in a dynamic, highly competitive and constantly changing market.

Significant volumes of many chemical substances are intermediates, used only for the production of other products. Some of these are in fact onsite intermediates, used within the same plant boundary, for the production of other chemicals. In those cases, their environmental risks are significantly different than those that end up ultimately in consumer products. And the gamut of chemical products runs all the way from those onsite intermediates through products that do end up in grocery stores. The needs, therefore, for testing chemicals can't be prescribed by formula. It has to take into account the conditions of use and the extent of environmental exposure. This is a matter of informed judgment.

Testing is sometimes hard to do accurately. Tests in some instances will produce false negative or false positive results. Test animals do not always react the way humans would. Some substances are more toxic to humans than to test animals, and some are less. We know that some people are repelled by tests on helpless animals.

Some chemicals are so reactive or unstable that they can't be tested. They may react with air or water and be impossible to test. In such instances the chemical substances produced by those reactions, if their toxicology is well known, then there is no mystery and no need for further testing.

We think in light of all of these circumstances that structural relationships and structure activity relationships are a powerful tool for helping to determine the toxicology of many related chemicals, especially when they are members of well-tested classes. We don't think the structure activity relationship is the final answer or total answer, but it is a powerful and useful tool.

If we look at the overall results, I think the answer is reassuring. None of the studies of the process to date have charged that it is not working. Many questions have been raised about the adequacy of test data and adequacy of data for new chemical substances, but there is no evidence and no example of where the system has failed, and not one shred of evidence to indicate the statute is deficient.

I would like to comment very briefly on the reaction to the bill on the part of environmentalists and industry. Some environmentalists, Terry included, are disappointed. They tend to forget that there are dozens of other statutes that come into play to control toxic chemicals, including, of course, the Clean Air Act, Clean Water, RCRA, FIFRA, Food, Drugs and Cosmetics Act, controls of the Consumer Product Safety Commission, and so on. But people often overlook several other powerful factors that have a great deal of influence in this area.

Concern over product liability suits imposes pervasive constraints on the chemical industry. The hazardous material regulations of the Department of Transportation are a major consideration. Why make it if you can't ship it? Our customers play a major role. They want to know the health and environmental effects of what they buy in order to protect themselves, their employees, and their customers. If they don't find out from us, they will buy from one of our competitors. Of course, people in the chemical industry do have a sense of morality.

Some of the critics of the act have a body count mentality. They want to see chemicals that have bitten the dust. They want bodies; you know, chemical industries dangling in the wind. They are disappointed, I am afraid to say, that this hasn't happened.

They forget that chemical producers have strong motives to make sure this doesn't happen. The chemical substance which is challenged by EPA is likely to have a hard time in the marketplace. Tests mandated by EPA will take longer than tests voluntarily undertaken, and they may cost more. The filing of an ineffective premanufacturing notice is likely to exceed the cost doing it right the first time.

The statute in this respect is designed to rely on discussion, negotiation, and conciliation rather than adversarial confrontation.

You asked earlier what does EPA do when they get a new substance with a PMN and a new substance with no test data and they have questions. In our experience, they will call up the company and say what are you doing here? You better come in and tell us why you don't have any test data on this totally new substance. In my experience, the company has either explained good reasons for that or gone back and said well, we will withdraw it. We better run some tests. We don't want to run the risk of having you zap us with a regulation if we can avoid it.

From the industry standpoint, living under TSCA is not as bad as many thought it would be. No one's worst fears have yet materialized. For responsible chemical companies, the enactment of the statute caused evolutionary, not revolutionary, changes in the way they did things. While there may be exceptions, the industry people who are involved have a considerable, perhaps sometimes reluctant, respect for the professionalism and competence of the people at EPA who are involved in this program.

I also want to say I have yet to find anyone in the industry who believes the people in the agency are pushovers from our point of view. But it is significant there has not yet been a single legal challenge to any of the orders issued by the administrator under the PMN program. There is great respect in the industry for, and understanding of, the fact that the agency has a big club in the closet, available for use whenever it is necessary.

In my view, the statute has stood the test of time very well. None of the responsible administrators of the agency over two administrations has complained about the lack of authority or recommended any significant changes in the law.

I continue to believe that the statute is effective, useful, and working. This doesn't mean there is an absence of controversy. Chemical companies, and others affected by the EPA administration, interpretation, and application of the statute, often object that the agency is overreaching and overreacting. Environmental groups complain it is not doing enough.

That is the way it ought to be. It leaves the agency in the uncomfortable, but thoroughly tenable position, of being midway between the extremes.

I would be glad to respond to any questions.

Senator **Durenberger**. Thank you very much.

Let me begin with a general purpose question. In my opening statement on Wednesday, I indicated that the primary thrust of these series of hearings was educational and indicated that Senators shouldn't waste their time being educated, unless there is some purpose to it.

Now, I don't really agree with that theory. I think there is plenty of room for education in our lives. But we are also concerned about periodically oversighting this process to find out if there isn't a way to make it work better.

It seems to me, as I listen to these two statements, I am having some problem figuring out whether we should just be satisfied with education or we ought to somehow, either through the authorization or appropriations process or in some other process, take another step.

Mr. Kenney, I think, just said no administrator has ever recommended any changes in TSCA. It is effective; it is useful; it is working. The fact that people on one side don't think it is working well enough, and people on the other side think sometimes it works too well, is a testimony to the fact it was well drafted by Mr. Davies and others in the early days. So this long process of three sessions of congressional debate probably created what: Some miracle piece of legislation here that is somewhere near perfection.

I have heard other witnesses, almost every witness, refer to this as gap-filling legislation. One of them earlier on implied that the reason there aren't recommendations and the reason there are some problems being testified to here is that EPA has its hands full with other things. This was just sort of the last one to fall into place.

So, Mr. Davies, maybe in part in what he said, but also in part how he said it, seems to have some harsh criticisms about the way the act is being implemented. So let me start out with a question to Mr. Kenney, which is sort of aimed at some of the good things that happened that don't necessarily happen right out of what EPA does.

I am told that when TSCA was originally being debated and discussed, the chemical industry took the position that TSCA really wasn't necessary, that firms were already performing adequate testing, and that included testing new chemicals. I guess I am curious to know from your experience, Mr. Kenney, whether or not the existence of TSCA, you said it was evolutionary, not revolutionary, but in light of what a lot of people in your industry said about the need for TSCA years ago, as against what is actually happening out there, have there not been some substantial benefits within the industry because of TSCA? Has TSCA changed the incentive to conduct testing within the industry? Are you more or less likely to test independently, or are you just sitting around waiting for EPA to tell you what to do? What is the situation in your own company or in the industry generally?

Mr. KENNEY. It is evolutionary, but the statute has brought about some significant changes. Companies do more testing today than they did 7, 8 years ago. They eliminate products from the development process sooner today than they would have 8 years ago. A chemical that is making its way through the research and the R&D labs that would appear to pose toxicological problems is apt to get dropped from the company's development consideration at a much earlier stage now than would have happened 10 years ago. And TSCA is a part of that. Because unless the managers can see a marketplace for a product that will cover the cost of development, including the cost of testing, they are going to drop it from consideration.

Most major chemical companies informally indicate, and it is certainly true in ours, that we have stopped development and research work on products, products that the researcher himself thought were highly promising inventions. In that sense the statute inhibits innovation. The researcher says, "Boy, you knocked my product in the head, and I had a real winner going for us." The environmental managers and the business managers say, "Yeah, but it would never stand the cost of testing or toxicology is too difficult." And it isn't just TSCA, of course. The concern about product liability suits comes into play.

But companies are doing more testing and they are watching their research projects more carefully with respect to the toxicology of the things. This is even pretesting, based again basically on the structure activity relationship. The company toxicologists look at products under development and they say, "Look, this one we are going to have to do a lot of testing on."

Senator DURENBERGER. Unless your testimony be left with the implication that in many cases this whole process impedes innovation, if would seem to me that there is also an opportunity for it to be an incentive to innovation. I mean, if clearly there is a national commitment to solving the problems of toxicity, that company in a very competitive environment which can lab up its R&D efforts to meet that kind of challenge is going to be out ahead of everybody else. Isn't that correct?

Mr. KENNEY. Of course.

Senator DURENBERGER. Is that happening out there?

Mr. KENNEY. Certainly. It encourages the innovation for products or substances that have less toxicity.

Senator DURENBERGER. Are there problems in the way the act is being implemented that in your opinion—and you may answer, and then I will ask Mr. Davies to make a similar observation about the industry—that would get in the way of that latter kind of innovation, the rewards to the good lab, the rewards to the really good company that does its toxicology work, that makes the commitments to testing, that shares the information about that testing with EPA and with others where appropriate?

Mr. KENNEY. Yes, I think there are things that the agency can do. Their present proposals to grant some generalized exemptions for onsite intermediates, other intermediates on polymers, will enable the companies to focus their resources on the areas that pose the greater danger. So yes, I think there are some improvements that can be made. I don't think they need to be statutorily driven. I think the agency has the capability of doing it.

Senator **Durenberger**. Dr. Davies, would you in a general way respond to the question on that first and then the sort of semi-specific follow-up to it?

Dr. **Davies**. In terms of the effect on the industry, Jerry and a number of other people in the industry have been telling me for a long time that it has had those kinds of impacts. I have no reason to doubt them. I think it has. But given what comes out on the public record, what the record seems to emphasize is what a low base we are starting from in terms of the amount of testing done and the amount of scrutiny given to chemicals.

I have urged CMA over the last few years at least to try to make public more data about the kinds of effects that TSCA, or TSCA plus whatever other forces are at work, has had on the industry in terms of testing and chemicals dropped and so on. They did do a study which was released 3, 4 months ago, but it frankly was not very informative. It indicated a fair amount of money was being spent annually by the industry for testing, but it remains a mystery at least to me what kinds of products at what stages are being tested. Clearly not new chemicals, because we have the data on new chemicals from the PMN. There isn't a lot of testing there. It doesn't seem to be existing products very much, or at least we don't have any documentation that I am aware of, or even anecdotal examples of existing products being pulled off the market for toxicity reasons. Maybe what is tested is the competitor's products. I don't know. But I think the overall impact on the industry has been beneficial, and I think there have been changes.

One other thing I might mention, following on Jerry's comments, is that while we still don't know a whole lot, "we" being people outside the industry, about the process of review and testing and what have you within the industry, at least in any kind of systematic way, we knew even less about the whole area of chemicals and toxic substances in the period 1970 to 1976. And yes, there was 6 years of review and the act was passed three times in the House and three times in the Senate. But at that stage of the game, and even in 1976, the estimates of the number of new chemicals varied from 100 a year to 10,000 a year. Nobody knew how many chemicals were going to be on the full inventory. And again, the estimates ranged all over the place. We just really were very ignorant about what kind of a problem we were dealing with and what the universe looked like.

We now have a much better fix on that. I think some of the things we have learned in the intervening years are some of the reasons why it is time to take a look at whether there are statutory changes needed.

Senator **Durenberger**. Dr. Davies, I am intrigued by your suggestion in your written statement, and this is one of the issues I raised in my opening statement, that the interagency testing committee be provided more industry data about chemicals before it makes its recommendations.

You also suggested that EPA be authorized to require testing by administrative order rather than by rule.

I wonder if you would elaborate a little bit on how these suggestions relate one to the other, and how they relate to EPA's present practice of using negotiated testing agreements in lieu of test rules.

Dr. DAVIES. Both suggestions are designed to simplify, clarify and improve the entire procedure for getting chemicals tested, particularly existing chemicals. If the industry data were available to the ITC, that would have two effects.

First of all, it would improve the quality of the nominations made by ITC. That is the primary point I make in my testimony. Therefore, presumably there would be a better batting average on the part of the ITC in terms of having EPA agree with the ITC that the chemical needs testing.

The other thing, though, is that if the ITC nominations were improved and had better information behind them, EPA's task of supporting either an order or a rule to require testing would be much simpler because, in effect, the ground work in terms of analyzing the information, having the information available, and what have you, that ground work would have been done for them to a great extent by the ITC. So it would improve the process in both of those respects.

I don't think it would do away with the need to simplify EPA's procedures for promulgating a section 4 rule because the rulemaking process in EPA is a cumbersome and time-consuming one, as you well know. It seems to me that the rulemaking process is probably not warranted in this instance, particularly given the ITC's screening procedure and the kind of process that the act sets up for section 4 testing.

If it were easier for EPA to promulgate testing rules or testing orders, then clearly that would greatly reduce the reasons the agency would have to go to some kind of negotiated testing scheme. The main reason that the agency has to go to that is how difficult it is for it to get a rule out. If it is easier for it to do that, then clearly there is less incentive for it to try and negotiate testing by the industry.

Now, as I say in my testimony, I think there are both advantages and disadvantages to negotiated testing. Some of my environmental colleagues would not make that statement.

The two main disadvantages of doing the testing through some kind of negotiated or voluntary agreement are, first of all, that there is no enforcement or sanction power to make sure that that testing gets done. To me, that is troublesome, but not likely to be a major difficulty. Frankly, the process is visible enough and I think there is likely to be enough pressure on what is basically a pretty responsible industry, so that their outright reneging on some kind of testing agreement is probably not a likely outcome.

Much more troublesome is the fact that the act ties the section 4 testing rule into a number of other authorities contained in the act. For example, if a testing rule is promulgated for a category of substances, the PMN for a new chemical that is in that same category must provide that same testing information. There are a variety of connections of that sort. None of those connections are triggered or take place if the testing is done by voluntary agreement.

To me, that is the major drawback. It is a significant reason why it is preferable to do testing formally and by rule rather than by a negotiated agreement.

Senator DURENBERGER. Mr. Kenney, would you have any comment on that?

Mr. KENNEY. Yes; first, with respect to the interagency testing committee, I think basically I agree with some of the points made by Jerry in his statement. The Chemical Manufacturers Association has in fact suggested a change in the procedure used by the ITC in order to meet these problems.

What they have suggested, as I understand it, is that the ITC engage in a kind of two-step process. Instead of stepping up to the bat every year and designating a list of substances that EPA has to decide whether or not they should be tested, the industry suggestion is that the agency issue a provisional list saying we are considering designating these substances and allowing then a period for comment. Then the agency, the EPA, the affected people in the industry, and others, can come back to the ITC and say the testing is already underway on this substance or nobody ever makes this one anymore, so that when they submit a list that the statute requires the agency to move on, the list will make better sense and be better focused.

We agree with that point, and the industry has offered suggestions to attempt to cope with it.

With respect to voluntary testing, we think it is going to work. We think it is working. I think, as a matter of fact, that 2 years from now the problem that is before this committee is likely to be the question of how is the agency going to manage all the test data it has before it, because there is a great deal of testing going on now. You heard Don Clay on Wednesday say that they have received, as a result of their recent order under the reporting sections, more than 450 toxicological studies. Within the next couple years, they are going to get an enormous volume of test studies. They are going to have a hard time coping with it. You and I and others may be beating them over the head not about getting more studies but what they are going to do with the studies they have.

There was a comment you made earlier. I suggest there is at least one other avenue of action open to you, sir, in connection with the way EPA administers this. You mentioned the oversight process and the appropriations process. You also have to confirm the administrators. If I read this morning's paper correctly, you have a new opportunity shortly in that respect.

Senator DURENBERGER. I hate to ask this question in light of what we just talked about in terms of generating information, but, Dr. Davies, apart from the comment that you made regarding the information or providing more information to the ITC, do you think EPA is using its information gathering powers of TSCA as fully as it should?

Dr. DAVIES. No; I do not. It depends what one encompasses in terms of information gathering powers. I do not go into it in either my written or oral testimony, but parts of section 8 have been effectively implemented, I think, and some parts of that section have worked better than I think anybody thought they would. Section

8(e) in particular has proven to be a tremendously useful source of information.

But clearly the information isn't coming on the new chemicals. We have been through that. And the hard data on the existing chemicals is not coming for the most part, either.

Jerry, I must admit, I would welcome the day when we were worrying about EPA dealing with all the test data that it had and beating them over the head because they weren't processing it fast enough or well enough. Unfortunately, given the weakness in terms of resources, of both skilled manpower and money, within EPA in general and the Office of Toxic Substances in particular, it wouldn't take a whole lot of information to bring that scenario about, I am afraid. So it may be more realistic and still not indicate we are getting enough information.

Senator DURENBERGER. Let me expand that slightly. You talked, in your statement, about a comprehensive strategy for dealing with toxic chemicals, that is one of the things that concerned us, to take this beyond just EPA and TSCA. You suggest TSCA is an important part of that strategy. I wonder if you would elaborate on that a little bit, and particularly indicate the relationship between TSCA and other laws, particularly in the area of information exchange and the regulatory coordination, and so forth. I will ask Mr. Kenney to make a similar observation.

Dr. DAVIES. I cannot give you a very good answer to that overall question because it is a very difficult, broad, and complex question as to what an overall strategy for toxic substances would look like.

We at the Conservation Foundation are just beginning to work on trying to develop some answers to that question. But my own conviction is that we really have not even begun the process—in this case "we" meaning the Government and the Congress and all of us concerned—of trying to figure out the statutory and regulatory implications that follow from the toxic substances problem. Acid rain, which is, granted, a major problem, is not likely to be equaled in scope very often, but it is, I think, a prototype in many ways of the environmental problems of the future. The characteristics of the acid rain problem are typical of the toxic substances problem in many ways, in particular the fact that you are dealing with a multimedia situation. Acid rain is an air pollutant; yet the effects are in water and on the land. So how do you set standards for it under an air pollution statute? The statutes are clearly not designed to deal with long-range transport problems. Those kinds of characteristics are true of a lot of the toxic substances as well, particularly the multimedia question.

So then the question becomes: How do you use a set of statutes which were designed to deal with one medium at a time, either air or water or land disposal, how do you use those to deal with chemicals that control actions can shift to different media or that can go from one media to another through natural processes? How do you try to deal with that?

At the Conservation Foundation, just to give you an example of the kind of thinking we are doing, one of our first steps is to try to take the Clean Air and Clean Water Acts and RCRA and put them together and see what a comprehensive multimedia statute would look like. That certainly is not going to be easy. It may not be possible at all. But once we have gone through that, then we would intend to look at TSCA and see what a comprehensive statute would look like and how it would relate to TSCA, or it may come out in fact looking very much like TSCA. As Jerry said, the act is very broad and comprehensive.

In terms of the specific relationship of TSCA to other statutes, there are two points. One, clearly the act was intended to serve as a way of providing information for the implementation of other statutes. That is in fact the rationale for the interagency testing committee. It gave other agencies a way of influencing EPA's process for obtaining information and therefore being able to use the information themselves. So I think that the fact that not as much information as was intended or is desirable is being generated adversely affects other programs as well as the program under TSCA. It does have an impact on other EPA programs and on other agencies.

The other thing is whether you need to change anything in TSCA itself. TSCA has a section, section 9, which deals with the relationship to other agencies. Section 9(b) deals with the relationship of TSCA to other EPA programs.

It has been claimed by Steve Jellinek, for example, and other people in a position to know that section 9(b) in fact was a significant impediment to taking action particularly under section 6. I am not a lawyer. My reading of section 9(b) is that it shouldn't be an impediment to anybody to do anything. It gives the administrator great discretion. I frankly don't understand why the agency should be so skittish about it. But there is that feeling. And I guess I would say that section 9(b) doesn't, in my view, contribute anything useful to the act and, therefore, I have recommended, for example to Mr. Florio's committee on the House side, that section 9(b) be repealed.

As I say, I would be hard put to make a case that it is an impediment, except that a number of people who have been in charge of implementing the act claim that it is.

Senator DURENBERGER. Before I turn to Mr. Kenney, did I hear you a couple minutes ago say we could use TSCA to handle the acid rain problem?

Dr. DAVIES. No; I did not say that.

Mr. KENNEY. I struck that out of my earlier draft.

Yes, as a matter of fact, the statute could be used.

Dr. DAVIES. It could.

Mr. KENNEY. Its powers and provisions are broad enough to deal with acid rain. No one has yet proposed it. No environmental group has filed the petition under the statute with that objective. I don't think it is necessarily well suited to deal with the problems of acid rain, but the power is there.

Senator DURENBERGER. Do you care, Mr. Kenney, to comment on this general notion of a more comprehensive strategy here in dealing with toxic substances?

Mr. KENNEY. No; Jerry is the innovator in this area, so I am waiting to see what the Conservation Foundation does. TSCA clearly has a role and it is playing a role. The information generated under TSCA today is useful in other EPA programs and in programs in other parts of the Government, including OSHA. It isn't something that overjoys me from where I sit, but it happens, and probably usefully in the public arena. We would rather do one set of tests for one agency than have to do three sets of tests for three agencies.

Senator **Durenberger**. Let me ask both of you something about the European system's potential contributions. Some people call this the pay-as-you-go system. That is having established a presumptive requirement that other tests are performed down the line at certain stages of chemical growth in the marketplace. Would you comment on the wisdom of this kind of approach?

Dr. **Davies**. I think it is a sensible approach. My understanding is that some consideration has been given within the Office of Toxic Substances to taking this approach at least for some kinds of chemicals.

I think one fact, though, should be brought out in this context. That is that there is, I think, a general impression that all of the PMN's come in as very small volume chemicals, that all chemicals start out very small and big ones only get big over a long period of time. I think that was more true in the past. If you look at the PMN submissions, those that do give production volumes and don't classify the production volume as a trade secret, some significant portion of those PMN's are large volume products to begin with. I haven't done the analysis. As far as I know, neither has anybody else. But my guess would be that probably 15, 20 percent of the PMN's are in fact fairly large volume chemicals to start with. So that if you take the sort of pay-as-you-go philosophy, there is at least some significant portion of chemicals that can pay a fair amount right at the start.

Mr. **Kenney**. In principle, it doesn't trouble me to do that. The statute in fact, it seems to me, makes provision for doing that kind of thing. The only problem that I would have, and we would have, would be to avoid doing that by automatic formula, simply because the conditions of use and the inherent toxicity of the substance have a great deal of variance on the kind of test you would run and the level of test and when it should be tested and whether it needs further tests.

Senator **Durenberger**. Are you referring to the SNUR authority?

Mr. **Kenney**. Well, both under SNUR and under section 4. The administrator has authority to get the information to monitor the growth in volumes of chemical substances, and he certainly has authority under section 4 to invoke test rules for those substances when they get the volumes that cause some concern. But to apply this by an automatic formula I think would be a wasteful way of doing it. On a case-by-case basis I think the administrator should.

Dr. **Davies**. Could you define categories of chemicals for collecting such information?

Mr. **Kenney**. If the law permits that, certainly I think you could. You are going to have a lot of argument about it. But I think it is a potentially doable thing.

Senator **Durenberger**. We have a problem with using the significant new use rule in that we have to go through the rulemaking process, and if we are going to do that on a chemical-by-chemical basis, it just takes us forever to implement what might be a good idea.

Mr. KENNEY. It doesn't have to be on a chemical-by-chemical basis. It can be done by a category basis. As I read the statute it could.

Dr. DAVIES. I think one of the proposed new use rules, Senator, does relate to a category.

One point on categories, though. It just came up I think in your conversation with the gentleman from GAO. One has to be careful about whether it is really worthwhile to regulate by categories. Clearly in a lot of instances, and new use rules I think is a good one, it is very efficient to use categories because you could cover a larger number of chemicals in one rulemaking effort. But one of the things that tied the section 4 procedure into knots under the former administration was that more time was spent trying to define and defend the designation of a category than would have been spent putting out the rules separately for each chemical covered. And furthermore, it wasn't clear what good it did to designate a category under section 4 and then test individual chemicals within that category in relation to further action. In other words, could you then take section 6 action for a chemical that was part of the category but not one of the individual chemicals tested? It is probably doubtful you could, in which case you really didn't save very much time by doing the testing for a category.

Senator DURENBERGER. I thought implicit in the response from one of the previous witnesses was it was all the fault of environmentalists. They won't let us get to a category. Is that true or not true? What is their concern?

Dr. DAVIES. That environmentalists object to regulating by category?

Senator DURENBERGER. I thought that is what I heard. Maybe I was wrong.

Dr. DAVIES. I think environmentalists generally have supported action by categories. If you are talking about exemptions, I think not. It depends.

Senator DURENBERGER. Mr. Kenney, let me ask you about something that is sort of a reflection again back on the testimony we heard earlier. You say toxicology testing where indicated, has been a routine procedure for many years, and TSCA for the most part only accelerated the trends. But the testimony I believe we heard from GAO or OTA, one or the other, was that only 17 percent of nonpolymer, high-volume, consumer-use PMN's had a mutagenicity test. We asked some questions about the problems.

When is toxicology testing indicated to a company, and do you think the amount of testing reported on PMN's reflects it is just a routine procedure being accelerated?

Mr. KENNEY. I am not in a good position to respond or have knowledge to respond fully to your question. Practices vary by company. I am really not sure how every company makes its decisions on when to test it and when not to test.

Senator DURENBERGER. Maybe I should save that for Monday.

Mr. KENNEY. I think you would get a much better answer from those people than you will from me, sir.

Senator **Durenberger**. Dr. Davies, as a closing question, what do you think are the two or three most important things that could be done both legislatively and administratively to improve protection of public health and the environment through TSCA?

Dr. **Davies**. As I indicated in my testimony, in my mind clearly the most important matter is to assure that adequate data are submitted on the PMN's. That is the No. 1 priority. I think there are a variety of ways that can be done, but something has to be done.

I am hopeful that under a change of climate there are at least some grounds for believing that something might be done.

Second, I would say with respect to existing chemicals, we need to try to think through the kind of overall strategy that I was talking about earlier. But then clearly there are problems out there that ought to be dealt with. The notion that section 6 has not been used because there aren't any unreasonable risks out there is in my opinion not valid. It obviously depends on what is the definition of unreasonable. But there are clearly problems out there, and something ought to be done about them, and nothing much is being done about them now.

Then, finally, I would say that in terms of testing, in section 4, there is a lot of work needed there as well.

Senator **Durenberger**. Mr. Kenney, I thought implicit in your testimony was the statement that TSCA does not need to be amended in any way. Is that correct?

Mr. **Kenney**. I think the statute is adequate. It can meet the problems. I am not going to defend everything the administrator has done, obviously, over the past 7 years.

The one thing I think they could do to improve the process significantly would be to adopt the rules with respect to some of these exemptions, so that the industry and the agency could then focus its attention on the areas of greatest concern. Because one of the real problems is a lack of resources, not just people in EPA but a lack of trained toxicologists, and testing facilities have at times been short. And to waste those resources on things that don't have to be done is unnecessary and foolish. By concentrating the efforts and focusing on areas of greatest concern, I think the agency can much better fulfill its mission.

Senator **Durenberger**. Dr. Davies, do you want to close with a comment on that particular issue?

Dr. **Davies**. We have supported the general principle of an exemption policy. But the proposed exemption rule that has been promulgated by the agency I hope will be modified when it becomes final, or at least will be reproposed. I think it was much too broad. In effect, it was a reflection of a philosophy which I hope is now gone from the agency.

Also I would hope, if nothing else as a token of good faith, that a properly crafted exemption policy would be accompanied by a nonexemption policy which takes steps to insure that testing data are submitted on the chemicals where you do need data. It seems to me that a good indication of a change of view within the agency would be if the exemption rule were accompanied by a proposed rule dealing with the lack of data problem.

Senator **Durenberger**. Thank you both very much for your time. I appreciate your responses.

Our last panel includes Mrs. Jerrothia Riggs, president, Camden Board of Education, Camden, N.J.; and Mr. Thomas J. Dawson, Wisconsin Public Intervenor, Madison, Wis.

I wonder, Marcia, would you mind coming up with this panel? I want to promote you from assignment to committee staff, if you would join this panel. It might be helpful to us if, after they are through testifying, and if you are willing, you would just in general react to some of their comments.

Ms. WILLIAMS. I have Ed Klein here with me. Shall we both come up?

Senator DURENBERGER. Great. Terrific. We will try to get the most out of the half hour or so that we have left.

We can use our 10-minute rule, Mrs. Riggs, which means that your statement will be made part of the record, and you can try to summarize it within 10 minutes.

Mr. Dawson, if you would do the same.

Then that leaves us approximately 10 minutes for our two friends from EPA to react to your testimony and to respond, along with you, to any questions we might have.

We welcome you to the subcommittee hearing. We look forward to your contribution to what I characterized earlier as an education. It is appropriate to have the president of the Board of Education come to educate the Senators. We thank you for being here.

STATEMENT OF JERROTHIA RIGGS, PRESIDENT, CAMDEN BOARD OF EDUCATION, CAMDEN, N.J., ACCOMPANIED BY OCTAVIUS T. REID, JR., DEPUTY EXECUTIVE DIRECTOR, NEW JERSEY SCHOOL BOARDS ASSOCIATION

Mrs. RIGGS. Thank you, Chairman Durenberger. I have with me Octavius T. Reid, Jr., deputy executive director of the New Jersey School Boards Association. I intend to summarize my remarks.

Asbestos is virtually everywhere. It is a widespread environmental contaminant for a major portion of our society. Asbestos has been used extensively in the public schools since 1946 for fireproofing, insulation, as well as decoration.

In 1973, the U.S. Environmental Protection Agency issued a ban on the use of sprayed asbestos because of the potential danger to our students. We must address the question of how to eliminate the potential danger to our students.

I have come here today to help crystalize in your mind the urgency of the asbestos situation, especially in New Jersey, where officials have not reacted quickly to the asbestos situation because it seems too innocuous. If asbestos gave off an obnoxious odor and if people were becoming ill instantly, there would be no question, action would be immediate. However, because the diseases of asbestos, mesothelioma and lung cancer, do not surface for 20 to 40 years, people are not cognizant of the true urgency of the situation. Asbestos workers come down with these diseases late in life, but the children now being exposed to these fibers will be in their prime years, their twenties and thirties, when breathing will become difficult and their lives may be shortened.

Many cases of badly damaged asbestos-containing materials have been found in schools such as is the case in our schools in Camden.

For example, you may recall seeing coverings around hot water pipes that lead into classrooms. If the student walks into it, kicks it, or bumps a desk or chair into it, that mild contact could be sufficient to release friable materials into the atmosphere which subsequently can be ingested and contained in the lungs. Even floor vibrations in multistory buildings could release friable asbestos fibers into the atmosphere of classrooms on lower levels.

Friable asbestos materials are especially common in overhead surfaces, ceilings and on the walls and pipes, such as the hot water pipes, which are at ground level, and thereby contribute to air contamination both from the ceiling and from the floor.

Why is this asbestos problem critical with children? In school buildings, the major occupants are children. Since their life expectancy is over 60 years, there is much time for the disease to develop.

Children are more susceptible to cancer because of rapid and abundant cell growth.

Since children spend a great amount of time in school, they could be exposed to high levels in contaminated areas.

The school population is intensely active. Students can cause destruction and flaking of fibers, thus contamination, with their normal activities.

Children who smoke and who are exposed to asbestos have 92 times the chance of getting cancer as a person who does not smoke and is not exposed.

Children have a higher rate of air exchange. They breathe up to three times the amount of air as an adult, thus breathing in more fibers.

Breathing increases with greater activity; thus children inhale great amounts while playing.

When excited or active, children tend to mouth breathe, thus losing natural nasal filtering.

Children are shorter, getting significantly higher exposure closer to the ground.

With respect to school buildings, the following problems exist. The most seriously damaged ceilings occur in schools. Vandalism in schools causes vast destruction on ceilings and ultimately contamination.

Because damage is likely in schools, concentrations of asbestos are likely to be significantly higher than outside air.

Air levels are significantly highest after contact: Sweeping, dusting, et cetera.

Twelve years ago studies in Connecticut showed a link between asbestos exposure and the development of mesothelioma in some 13 children. Even today there are no standards for exposure to asbestos that are exactly applicable to its presence in the air of public buildings such as schools.

In March 1978, the U.S. Environmental Protection Agency released its first guidance document entitled "Sprayed Asbestos-Containing Materials in School Buildings." The document discussed three ways to deal with asbestos: One, encapsulation; two, enclosure; and three, total removal.

Independent research done by Dr. Robert Sawyer of Yale University has shown that children may be exposed to an abnormally high number of asbestos fibers in schools where sprayed on asbestos surface materials are deteriorating due to the gradual breakdown of the bonding agent used in such materials. He has shown that such fibers remain airborne for long periods of time and may be reintroduced into the environment by means of the usual dry cleaning, dusting, and sweeping procedures that are used in schools. Then, too, maintenance and repair personnel may be exposed to high levels of asbestos fiber concentrations for short periods of time as they cut, drill into, sand, or even paint over friable asbestos materials.

As a result of the survey that was done in New Jersey in 1977, some 265 schools in 142 districts reported the presence of asbestos material. Subsequently, in 1978, the U.S. Environmental Protection Agency announced that it was going to require officials to inspect schools and remove dangerous levels of asbestos contamination. The plan was delayed and eventually dropped by the current administration. However, the EPA did announce a new regulation in May 1982 requiring each State to inspect all public school buildings by June 1983. That inspection has just been completed and the compilation of that data was, unfortunately, not available to us in time to report to you at today's hearing.

In addition to regulations, Congress recognized the need for legislation and in 1980 passed the Asbestos School Hazard Detection and Control Act, cosponsored by New Jersey Senator Bill Bradley, which was designed to develop a program of asbestos control and to provide funds for detection and abatement.

The act authorized $172.5 million. However, it required appropriations by Congress which, to my knowledge, never did occur. Because there was no funding appropriated, the Education Department relegated the informational program to a low priority, according to the General Accounting Office. As a result, Federal efforts to help solve the asbestos problem in schools have been of little help to States searching for ways to identify and deal with the problem. The 1980 law also provided for an asbestos hazard school safety task force, which was appointed by the Secretary of Education but has not met since 1980.

The EPA regulation in 1982 brought to public light renewed interest in the asbestos problem. As of this past June 1983, districts were required to post a notice in all school buildings warning that they contain asbestos where it has been identified.

Senator DURENBERGER. Mrs. Riggs, you are going to have to move to a conclusion in your statement because we have gone past the 10 minutes.

Mrs. RIGGS. All right. The estimates for removal of this problem in the public schools of New Jersey alone range as high as $50 to $70 million. I can't speak for what the cost might be in the other States of the Nation, but if that is what it takes to guarantee that our youth will have the same opportunities that you and I have had, I believe that to be a small price to pay. Only complete removal of asbestos will eliminate the risk of asbestosis or lung cancer or mesothelioma and insure our children of one less health hazard to face as they approach adulthood.

Mr. Chairman, I thank you for the opportunity to come before you.

Senator DURENBERGER. Thank you very much. Your full statement will be made part of the record.

Mr. Dawson.

STATEMENT OF THOMAS J. DAWSON, WISCONSIN PUBLIC INTERVENOR

Mr. DAWSON. Thank you, Mr. Chairman. In the interest of time, I will not read all of my statement. In fact, I am not even wearing my glasses. I will simply try and make my points very quickly for you. You have my testimony and I ask that it be placed in the record.

Senator DURENBERGER. It will be made part of the record.

Mr. DAWSON. As in many other States, Mr. Chairman, we have serious problems with toxic chemicals in our ground waters. Several years ago we have detected, and since that time have continued to detect, numerous pesticides in the round waters of Wis., especially in the Central Sands region. So far we have found up to seven pesticides in the ground water. Four of those pesticides exceed the drinking water guidelines; not standards, but guidelines issued by EPA.

We also have a very serious problem with other toxins in the ground water. Attached to my testimony is a laundry list, so to speak, of 44 chemicals that have been found in the ground water from one solid waste landfill, hazardous waste landfill, near Stoughton, Wis., which is only 10 miles from our State capital. Many of these chemicals I can't even pronounce.

In 1982, the Department of Natural Resources of Wisconsin also did a testing program of community water supplies, 208 in total. Out of that, 51 communities showed volatile organic compounds, VOC's for short, in those water supplies. As a result of that testing program, four community water supplies had to be shut down, and many of the small communities in Wisconsin are going to have to replace their wells at a cost of in excess of $625,000.

That may not sound like a lot of money in today's terms, but for a very small, rural community that is a lot of money.

That is not to speak about the human harm that is going on in Wisconsin. I have met with dairy farmers on the brink of bankruptcy as a result of toxic pollutants from mine tailings. I have met with a family that has been affected by that Stoughton site in Wisconsin. They are literally prisoners in their home. They can't sell their property because the ground water has rendered the value of their property useless. They have not had the money to even afford the amount of water that they need, and it is only because of the voluntary efforts of the water supplier that they are now getting water.

So we do have serious problems in Wisconsin as far as ground water and toxic substances in that water.

What we need in Wisconsin right now at least under the auspices of the Toxic Substances Control Act are two things: standards and monitoring. There are two kinds of standards that need to be set for drinking water. Wisconsin right now is under an effort to develop drinking water and ground water standards. However, what we need are standards developed by the EPA.

We need so-called Federal numbers, and the programs that are now being set up in Wisconsin are totally dependent on the development of these Federal numbers. When I say Federal numbers, I mean either maximum contaminant levels, suggested no adverse response levels, or risk levels for carcinogens.

We also need toxicity data. In the *Aldecarb* case where we had that pesticide in the ground water in Wisconsin, the State struggled to get as much toxicological and other data from EPA as possible and had a very difficult time getting that information. There was not a computer key that could be pushed to get the kind of information on Federal numbers and toxicological data that I think our State officials and even I would suspect most of the public would think would exist through the offices of EPA.

These numbers, especially maximum contaminant levels, do not exist for most toxic chemicals. Toxicological data are not readily available. TSCA provides that data are supposed to be available, but the States are having difficulty getting that toxicological data. There is no, like I say, central place to get that information. The States are having difficulty getting EPA to provide definitive statements about Federal numbers. Sometimes they are talking SNARL's. Other times they are talking MCL's. We need authoritative information along that line.

Then, much of the toxicological data which are available and which have been submitted to EPA do carry with them these requests for confidentiality status. We haven't got the time when we have a situation with certain toxic chemicals in the water to start issuing and seeking Freedom of Information Act requests to free that data up. We need that information right away.

Now as far as standards setting, we ask that two sets of standards be set. We need a maximum contaminant level, as the jargon is used by the EPA, which establishes the upper limit at which ground water can be certified to be relatively safe for human consumption. But we also need what is called a warning level, which is a percentage, which EPA suggested be 10 percent, which is a warning level at which certain mandatory actions would be taken in order to prevent ground water from ever exceeding the maximum contaminant level that would be set.

We ask that there also be coordination between the bureaus within the EPA to share information between themselves. It is not always the case that they do. Also, there is a need for immediate sharing of information of toxicological data with the States.

Again, Wisconsin is trying to set these standards. Yet we need that data. We need those Federal numbers in order to effectively do so.

Second, I mentioned monitoring. There are two kinds of monitoring that needs to be done for determining what levels of toxics are in the ground water. We need what is called ambient ground water monitoring, which means you go out and look for trouble spots throughout an area. Second, once you find a trouble spot, a toxic area, we have to do the kind of intensive monitoring that is needed to determine where the pollutants are going, how fast, what they are doing in the ground water, and so forth.

We need the ability and the authority to order monitoring of responsible parties when it occurs. It is well recognized that the people, the taxpayers, do not have the money to conduct that kind of monitoring. The people who are responsible for that pollution should take the responsibility for providing and paying for that kind of monitoring.

Again, I summarized the main points of my testimony. I thank you for the opportunity of appearing before you.

Senator **Durenberger**. Thank you very much.

If I might turn to EPA, and we have two somewhat different but related situations before us, one that goes specifcally to the asbestos problems, which I am sure you are familiar with, and the other a general statement of a problem. I wonder if you wouldn't be willing to tackle each of them separately and give us, not just a reaction to the testimony, but sort of an update, particularly with regard to asbestos. If somebody wants to start there with the status of the problem, where the concerns are, how this relates to the area of toxic substances, TSCA, and the other things with which we are involved here. Miss Williams?

STATEMENTS OF MARCIA WILLIAMS AND ED KLEIN, ENVIRONMENTAL PROTECTION AGENCY

Ms. **Williams**. Let me take a shot at it and then I will ask Ed Klein if he would like to add anything. He is Director of the Chemical Control Division, which is the division which was responsible for writing the asbestos in schools rule that was published May a year ago.

I think clearly the statement that I would want to make is that we do believe asbestos is a problem. There is no disagreement with that. As Don Clay said in his testimony on Wednesday, we are proceeding to look at asbestos in more than just the area of schools and plan to take some actions over the next year with regard to production use of asbestos.

I think with regard to the schools area one of the things that we have spent a lot of time on, starting back as early as 1977, is the whole area of getting the information base on which to deal with this problem. That information base has been helpful, but it has also shown to us that it is often very difficult to develop criteria by which one would say whether or not removal, for example, is the appropriate action or whether some type of containment is the appropriate action.

Clearly there are situations where removal is the appropriate action. However, when we started to develop a regulation in which to deal with this, it seemed that the most appropriate thing for EPA to do as a first step was to make sure that we could identify where the problem was. That is what we proceeded to do in that rule.

Our feeling was that we were dealing with a joint kind of a partnership situation between the agency and the States. This was looked at very carefully in the development of that rule because clearly once there is an identification of the problem, I think there are certainly different viewpoints as to whether the responsibility for, I don't want to say solving the problem, but dealing with the problem should be a Federal lead or State lead.

The one thing that EPA is firmly committed to doing and has continued to do is to provide a high degree of technical assistance to all States and local agencies that need information on how to identify whether asbestos is there and what to do in specific situations when they do find it.

Let me see if Ed wants to add anything else. I will try to answer any specific questions you have on it.

Mr. **Klein**. Yes; I would like to add one thing, with respect to the cost, because that seemed to be an important element.

Congressman Perkins, I believe, has held some hearings recently on the question of whether there would be any Federal funding. You may want to raise the issue with him in that forum as well.

That is really all I had to add.

Senator **Durenberger**. Let me ask you a specific question.

Ms. **Williams**. I do have two things, actually, that might be useful for you to know. One is we are going out with a survey on asbestos in public buildings to again continue to see whether or not we have a problem that needs to be pursued.

The other thing is that we also have plans over the very short term, 3 to 6 months, to go out with an evaluation of the rule that was put into place last year, the identification rule, to make sure that the appropriate kind of followup is happening. Obviously, that evaluation that we are doing should provide the ground work for trying to look at what appropriate next steps would be.

Senator **Durenberger**. Let me ask a specific question, which may seem small compared to the schools, but brake linings, for example, contain asbestos. When they are replacing them, the custom at least has been, or is, to blow the drum clean with compressed air, thus filling the air in the station or the shop, or whatever, with asbestos particles. Has the agency taken some specific action with regard to educating or otherwise addressing that specific problem for the people working with it?

Ms. **Williams**. Brake linings are clearly one of the areas that will be covered in the actions that we are looking at and that we plan to propose over this coming year.

One of the main issues involved with the brake linings is the question of substitute material availability. In some types of brakes there are substitutes available. In some types of brakes at this point in time we believe there still are not feasible substitutes available. This may be more appropriate from a regulatory standpoint at this time to deal with the brake linings through the use of a producation cap rather than an outright ban.

But those decisions are still in process and will be decided within the next 6 months when our proposed rules come out. There has been considerable discussion with various groups with regard to the problems of exposure from brake linings.

Ed, can you comment on some of the specific conversations on that?

Also, one of the things we have looked into is the possibility of putting out something that we call a risk management advisor; kind of an approach with brake linings to do exactly that, basically to provide education to the people most likely to be exposed to that particular use.

Mr. **Klein**. Clearly, as Miss Williams indicated, we are very, very concerned about brake linings. There does seem to be a downward trend in new cars in the use of asbestos in brakes. In most medium-sized cars and smaller cars, the front disc brakes have substitute materials in them. So they are at least in that regard being phased out. But I think the problem still does exist.

Senator **Durenberger**. Do you want to react to the comments made by Mr. Dawson? Are those typical of the comments made by frustrated assistant attorneys general in 50 States across this country? Is Wisconsin unique? What is being done to address some of these very specific concerns?

Ms. **Williams**. Let me try and answer generally for the agency, although I should stress, I think, that probably for many of these situations the Toxic Substances Control Act is not the most appropriate statute for dealing with some of these concerns. I am not trying to deemphasize the importance of the concerns because I think the concerns are real. But there is the Clean Water Act and the Safe Drinking Water Act and the FIFRA that in many cases are the more appropriate statutes to try to deal with some of these concerns.

Senator **Durenberger**. When we are talking about ground water?

Ms. **Williams**. Yes, when we are talking about ground water. And in particular, when talking about pesticide contamination of ground water, TSCA as it is currently written does exempt pesticide regulation under TSCA. So the appropriate statute would have to be FIFRA, both for collecting information on pesticides as well as dealing with developing tolerance levels or maximum contamination level kinds of issues.

So I would like to perhaps just provide general indications of areas where Mr. Ruckelshaus has indicated concern for these kinds of problems. One is he has set up two different task forces that are both on very short timeframes to come in with suggested approaches. One of those is a task force dealing with ground water. It is my understanding that he expects some recommendations from that task force in September. The other is a task force that has been set up on the concept of toxic integration. The idea there is that there are a lot of issues that are crossmedia, and it is appropriate to develop ways within the agency to raise these issues quickly, deal with their crosscutting throughout the agency, so that you have water and pesticides and perhaps toxic problems all together, figure out which is the best statute to take the lead on that, and make sure that we utilize the entire set of statutes to come to grips with the problem as soon as possible. The timeframe for that particular task force to get back with Mr. Ruckelshaus with recommendations in late October or early November.

So I think you will see, hopefully, some positive things coming out of these activities. It is a little difficult for me to react more specifically. I know there are activities going on in the Office of Pesticides with regards to working with the Water Office to set various kinds of acceptable daily intake levels and also with regard to looking at collection of various kinds of monitoring data. But I would have to provide additional information in a written response.

Senator **Durenberger**. Mr. Dawson, why don't you give us some advice for one of those task forces. We all care a great deal about the ground water problem. We don't want it to fall between Federal statutes. Do you have some specific recommendations that relate to TSCA, for example?

Mr. **Dawson**. The main response I have is there is a definite linkage between the information, the data, the toxicological data, on toxic substances that should and must relate to setting drinking water standards or what we call MCL's. We need to have these MCL's based on the kinds of toxicological data and other relative data that are going to be generated under the auspices of TSCA.

I am not convinced that that linkage right now is drawn. There are, for example, no MCL's or drinking water standards for the pesticides that have been found in Wisconsin ground waters.

Now yes, I realize that that is FIFRA. But the point is the same. That is that we don't have a drinking water standard issued by ODWS in EPA. What we have is OPP saying we have a drinking water guideline. It is a SNARL, a suggested no adverse response level.

There needs to be that sharing and linkage between what is happening in TSCA with what is happening in drinking water.

Ms. **Williams**. Again, TSCA and FIFRA are both very good mechanisms for getting information, toxicological information. FIFRA has in fact even an easier time of it than TSCA, in my opinion, in obtaining that information quickly.

The only point I would stress is if it is a pesticide that we need to get the information on, we have to use the FIFRA authority to get it. We have had some very preliminary conversations with the Office of Water, actually that go back more like about a year ago, with regard to the fact that TSCA would be a useful statute to obtain that information under for nonpesticides. We plan to continue those discussions in the near future.

Again, as Don Clay pointed out Wednesday, we think that is a major role that TSCA can play for nonpesticides.

Senator **Durenberger**. We have some potential problems with Senate rules if we go beyond noon. I have just one question I sort of left hanging in that Mrs. Riggs' statement is very complete on the problems and so forth with asbestos. I am left a little unclear right now about on whose desk it is at the Federal level, mine or somebody's out there in the bureaucracy. Where is the sign saying "The Buck Stops Here" right now on the asbestos problem?

Ms. **Williams**. You mean with regard to the cost issue?

Senator **Durenberger**. On the whole thing. Is it all over the place so that everybody keeps shifting the blame and says well, it is difficult to determine what the States are going to do?

Ms. **Williams**. I think the rules we have in place which required all schools to inspect by June of 1983, and obviously the date has passed for that, EPA has begun its enforcement effort to find out exactly the degree of compliance with that rule. As I said, we are also doing an evaluation to see whether or not we believe the rule has done what we hoped it would do in terms of getting action started. So I guess those two things are on EPA's plate.

With regard to the funding question, Ed, can you give us a more specific statement on the funding? That is not on EPA's plate.

Mr. **Klein**. I don't want to play an I-got-it-you-take-it routine, which I think you were alluding to. But in terms of funding, there is a law on the books. There is a Federal task force which is headed up by the Department of Education. So with respect to funding issues, I think the Department of Education is probably the place where you can get better information.

Senator **Durenberger**. Mrs. Riggs, do you want to respond?

Mrs. **Riggs**. Actually, Mr. Durenberger, the collection of information has been going on for 10 years or more than 10 years. We still do not have a set of standards. Basically so far as funding, actually programs that have been established up to this date do not work.

In a State like New Jersey, and I will use my own district to stress it, in the district where we receive 80 percent of our funds from the State because of our inability to raise resources, we cannot afford and we are not receiving anything from the Federal Government to actually suffice in identifying, much less following, any guidelines. We don't have it.

The other thing I would like to stress—and I am stressing this from possibly the humane standpoint—is that the concentration of this problem of asbestos in the schools primarily affects two types of people: one, our staffs; two, our children. That is for 180 days a year, which is required, mandated, you name it, for a period of 12 years.

I reiterate again: Programs that have been set forth have not worked. There is no specificity to the actual so-called rules and regulations.

Mr. **Klein**. May I add one thing?

Senator **Durenberger**. Yes, sir.

Mr. **Klein**. With respect to the EPA role, you are absolutely correct, Mrs. Riggs, that these are very, very complex issues that confront each of the schools. Just to give you some sense for it, it is even infinitely more complex trying to deal with it on a piece of paper from Washington.

Senator **Durenberger**. Unless it is a check with a signature.

Mr. **Klein**. That is probably right. But just from a technological standpoint, it is very difficult for us on a piece of paper to be able to predict precisely what type of abatement activity, if any, is appropriate in the school.

What was contemplated by our rule was that the people who have hands-on involvement would bring in experts to take a look and really make informed judgments as to what type of abatement activity, if any, is really needed. We make EPA personnel available to provide assistance for that. We provide technical guidance documents. By the way, a brand new one was issued this past May. We try to provide whatever assistance we can to help with those situations. But in the end, the decision can't be made from an office in Washington. It has to be made on the site of the school, making rational judgments as to what really needs to be done in that particular school circumstance.

Senator **Durenberger**. OK.

Mr. **Reid**. Mr. Chairman, if I could make one statement in response to that, because it is about to make me blow a gasket to a certain extent.

The major problem that we have in the schools—and regardless of where they are, New Jersey or anywhere in the Nation—is knowing the point at which the concentration of asbestos in the schools represents a health hazard to our students and our staff. One would expect that the responsibility for determining that level would be with the experts here in Washington, EPA. It does not make sense for 20,000 school buildings or hundreds of school districts, thousands of school districts, across the Nation to be individually trying to determine when it is necessary to abate that problem. That is why we come to you for guidance.

In the meantime, what we have gotten is a rule from EPA. And I understand they may be well-motivated, but their rule does the exact opposite of what they purport to try to make happen, because by posing that rule and suggesting that there is an asbestos problem, having known for the last decade or more that that is going to be a significant danger especially to kids, more so, because research has already shown it, to kids than any other segment of the population, because of having posted that notice, the only thing that we will have accomplished is to begin alarm in our communities. You then have the staffs who don't want to show up. You have the potential of lawsuits because of the exposure. And you have kids who are afraid of what is going to happen, knowing full well they will never really have an opportunity to understand it until 20, 30, or 40 years later.

Having raised that community activism and concern and anxiety, what are we left with? Nothing. We do not have a single guideline that tells us that is what we can do about it. If we did have the guideline, we then still have the subsequent problem of where do we get the funds to remove it.

Senator DURENBERGER. Thank you all very much. I will say to each of the panelists that you certainly should feel free to submit additional opinions for the record. We also may have some questions for each of you, answers to which will be placed in the record at this particular point.

This concludes today's hearing. Our next hearing will be Monday morning at 10 o'clock. Thank you.

[Whereupon, at 12:08 p.m., the subcommittee was recessed, to reconvene at 10 a.m. on Monday, August 1, 1983.]

[Statements submitted for the record follow:]

UNITED STATES GENERAL ACCOUNTING OFFICE

WASHINGTON, D.C. 20548

FOR RELEASE ON DELIVERY
EXPECTED AT 9:30 A.M. EDT
JULY 29, 1983

STATEMENT OF
J. DEXTER PEACH, DIRECTOR
RESOURCES, COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION

BEFORE THE
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT
OF THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

ON
GAO WORK RELATED TO THE TOXIC SUBSTANCES
CONTROL ACT AND THE FEDERAL INSECTICIDE,
FUNGICIDE, AND RODENTICIDE ACT

Mr. Chairman and members of the Subcommittee:

We are pleased to be here today to provide a brief overview of the work we have done on the Environmental Protection Agency's (EPA's) implementation of the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act.

TOXIC SUBSTANCES CONTROL ACT

Since its enactment in 1976 we have issued four reports on certain aspects of TSCA. These reports have addressed EPA's efforts to implement the legislative requirements of the act, EPA's regulatory action on specific chemicals, and EPA's use of voluntary testing agreements. I will briefly summarize each of these reports.

Status of TSCA implementation

Our initial work concerning TSCA resulted in the report we issued on October 28, 1980, entitled " EPA Is Slow To Carry Out Its Responsibility To Control Harmful Chemicals" (CED-81-1). The objective of that work was to determine the status of EPA's efforts to implement the Toxic Substances Control Act and to identify major issues confronting EPA in implementing the major program requirements concerning the screening of new chemicals, and information reporting, testing, and control of existing chemicals. The report concluded that because there was no clear sense of direction to guide the program and because of organizational and staffing problems, EPA had made limited progress in identifying and controlling existing chemicals and in developing a program to control new chemicals.

The recommendations in this report were directed toward the EPA program for screening new chemicals and called for EPA to (1) develop a strategy to obtain needed information on new chemicals using all TSCA authorities and (2) establish evaluation criteria for each decision point in the premanufacture notification review process. Since this report was issued, the premanufacture notification review process has been evolving and we are now conducting another review, which I will discuss later, of EPA's premanufacturing notification process.

Since this initial report, we have issued reports on EPA's efforts under TSCA to regulate two specific toxic substances--polychlorinated biphenyls and asbestos.

Polychlorinated biphenyls

Section 6(e) of the act directed EPA to control the manufacture, processing, distribution, use, and disposal of polychlorinated biphenyls (PCBs). In our December 30, 1981, report entitled "EPA Slow In Controlling PCBs" (CED-82-21), we stated that (1) EPA has made limited progress in implementing the legislative mandate to control PCBs, (2) EPA has little assurance that industry is complying with its regulation, and (3) EPA's enforcement program lacked overall direction and did not encourage quick compliance.

The report recommended some specific actions by the EPA Administrator to provide for more effective use of the agency's limited enforcement resources and encourage greater compliance with PCB regulations. These included (1) issuing revised guidance to enforcement personnel, (2) developing an information system for PCB enforcement, (3) providing earlier notification of violations so that corrective actions can be speeded up, and (4) reviewing and revising EPA's PCB penalty policy and its application to better encourage compliance. EPA has made some changes and has indicated that it is in the process of making other changes in the PCB inspection and enforcement program and its penalty policy that will be consistent with the recommended actions.

Asbestos

On August 31, 1982, we reported on EPA's efforts to address the potential health risks associated with asbestos-containing materials that were sprayed on walls and ceilings to fireproof, insulate, soundproof, and decorate many schools that were built or renovated between 1946 and 1972.

Our report, "Asbestos in Schools: A Dilemma" (GAO/CED-82-114), stated that, by requiring all schools to be inspected for asbestos and parents and employees to be notified if asbestos is present without specifying when asbestos is hazardous enough to warrant abatement actions, EPA has created a serious dilemma for school officials.

When schools are inspected as required and found to contain asbestos, the school officials are faced with the decision of what to do about the asbestos. Our review found that the lack of definitive Federal criteria has resulted in States and localities using different criteria in arriving at their decisions. The report concluded that until EPA develops more specific criteria about when the asbestos poses a problem and what actions are most appropriate, school officials may continue to overreact and spend money needlessly or, more importantly, underreact and expose school occupants to hazardous asbestos conditions.

We did not make any recommendations in this report because EPA was doing research on this issue and expected to validate what it believed to be a promising quantitative measure for assessing asbestos exposure and to issue guidance based on this measure.

This measure has since undergone validation tests, and it has been shown to be an unreliable indicator of asbestos exposure. In March of this year, EPA published a document, "Guidance for Controlling Friable Asbestos-Containing Materials in Buildings," that provides information on asbestos used in buildings and describes in qualitative terms the types of conditions under which the asbestos may pose a health risk and the kinds of actions, such as encapsulation or removal, that might be considered for reducing or eliminating such risks.

Voluntary testing agreements

Our most recent report entitled "EPA Implementation of Selected Aspects of the Toxic Substances Control Act" (GAO/RCED-83-62) was issued on December 7, 1982, to the Chairman of the Senate Committee on Environment and Public Works. The chairman asked us to determine if EPA had the authority to use negotiated testing agreements with the chemical industry to obtain needed health and environmental effects tests for chemical substances in lieu of issuing administrative rules formally requiring such testing. The report presented our assessment that the Toxic Substances Control Act does provide EPA with the authority to obtain necessary testing through negotiated agreements instead of administrative rulemaking. The report did not assess the appropriateness of EPA's use of negotiated test agreements in specific instances but this is being addressed in our current work.

Work in progress

Currently we have two reviews underway dealing with TSCA. One is an assessment of EPA's new chemicals program and the other focuses on how EPA is using its various TSCA authorities to investigate and regulate existing chemicals.

Our work on EPA's new chemicals program addresses the major differences between the EPA program for assessing new chemicals and the program adopted by the European Economic Community, and the adequacy of EPA's efforts and approach to protect against unreasonable risks to health and environment from new chemical substances. For example, EPA relies on structural activity relationship analysis to screen new chemicals whereas the European Community requires mandatory testing of new chemicals.

Our work on EPA's existing chemicals program addresses (1) how EPA is using its various authorities under TSCA to develop adequate data on the effect of existing chemical substances on health and environment and to regulate chemical substances that present an unreasonable risk of injury to health and the environment and (2) major obstacles to effective TSCA implementation and the range of actions that could be undertaken to overcome these obstacles. Two issues that will be addressed in this work are (1) priority setting for EPA work on existing chemicals and (2) the appropriateness of the manner in which EPA is using voluntary agreements with industry to test and/or control chemicals in lieu of requiring these actions through administrative rulemaking.

We hope to issue reports on the results of these two efforts by the end of January 1984.

Let me turn briefly to our work related to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Since the early 1970's we have issued 17 reports on FIFRA and EPA's efforts relative to it. For the most part, these reports have addressed one or more of the following.

--The registration, control, and use of individual pesticides.

--EPA's policies and procedures for registering and reregistering pesticides and their effectiveness in protecting public health and the environment from unreasonable risks associated with pesticides and their use.

--The effectiveness of EPA's efforts to enforce the requirement for pesticide registration and compliance with the conditions of individual pesticide registrations.

During the past two years, we have issued two reports on FIFRA--one on EPA's enforcement efforts and the other on pesticide applicator certification.

Enforcement

Our report "Stronger Enforcement Needed Against Misuse of Pesticides" (CED-82-5) was issued on October 15, 1981. It concluded that although enforcement of Federal pesticide laws is a key factor in ensuring that the public and the environment are not unnecessarily exposed to hazardous pesticides, EPA and the States do not always properly investigate cases and sometimes take questionable enforcement actions.

The report made a number of recommendations for improving the pesticide enforcement program, and EPA has taken actions to improve the enforcement program that are consistent with our major recommendations. These actions included

--providing improved guidance and training for enforcement personnel,

--implementing needed improvement in recordkeeping and reporting systems, and

--strengthening coordination with the Food and Drug Administration (FDA) and improving management controls over FDA referrals of suspected pesticide misuse.

The report also discussed the increases that were occurring in special registrations--that is registration of pesticides for special local needs for which there is no Federal registration--and questioned whether through special registration the requirement for Federal registration was being circumvented.

Applicator certification and training

Our most recent report, "Better Coordination Is Needed Between Pesticide Misuse Enforcement Programs and Programs for Certifying and Training Individuals To Apply Pesticides" (GAO/RCED-83-169), was issued on July 1 of this year. FIFRA provides that pesticides registered by EPA for restricted use can be applied only by individuals (pesticide applicators) who have been certified as competent to handle and apply these pesticides without harming the public, the environment, or themselves. Except for two States, the certification of pesticide applicators is carried out by State agencies. Under FIFRA States assume responsibility for applicator certification and training programs by submitting a program plan that is approved by EPA as conforming to EPA's established certification standards. EPA carries out the certification of applicators in the two States--Colorado and Nebraska--that do not have approved plans. The report states that the two States we visited (1) were not routinely and systematically developing the pesticide misuse data that is necessary to ensure that the certification and training program was adequately addressing the major misuse problems being experienced by the State and (2) were using some certification tests for commercial applicators that were not adequate for assessing the individual's competency to safely handle and apply restricted-use pesticides. We recommended that guidance be developed for EPA regional offices to assess State efforts in these two areas. EPA agreed with our findings and recommendations and indicated that it would act on the recommendation.

Currently, we are not doing any FIFRA related work.

Mr. Chairman, this completes my prepared statement. We shall be glad to answer your questions.

TESTIMONY OF MICHAEL GOUGH, SENIOR ASSOCIATE, OFFICE OF TECHNOLOGY ASSESSMENT, UNITED STATES CONGRESS, BEFORE THE SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT, COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS, UNITED STATES SENATE—JULY 29, 1983

The Premanufacture Notice (PMN) Program is the U.S. Government's effort to identify toxic substances before they enter commerce, to impose controls when necessary, and thereby to reduce unreasonable risks to human health and the environment. The Toxic Substances Control Act (TSCA) requires that a PMN be submitted to the Environmental Protection Agency (EPA) at least 90 days before a new chemical is manufactured or imported into the United States.

Using the information in the PMN and professional judgment, EPA reviews each PMN to determine if the chemical described in the notice presents or may present an unreasonable risk to human health or the environment. When EPA does not conclude that an unreasonable risk may be associated with the substance described in a PMN, manufacture of the chemical can begin at the end of the 90-day review period. In the event that EPA determines that the substance presents or may present an unreasonable risk, the agency can regulate its manufacture, processing, use or disposal.

THE OFFICE OF TECHNOLOGY ASSESSMENT STUDY OF PREMANUFACTURE NOTICES

At the request of the Chairman of the Subcommittee on Commerce, Transportation and Tourism, United States House of Representatives, the Office of Technology Assessment (OTA) examined the information content of PMNs. The OTA background paper, entitled "Information Content of Premanufacture Notices," was written by J. Stedman Stevens and me, and we were assisted in computer programming and analysis by John Bell. The first draft of the paper was completed in December 1982, and it was reviewed by about 30 individuals and organizations, including trade associations, environmental organizations, a trade union, and the EPA. The paper was published and released in April 1983.

INFORMATION TO BE INCLUDED IN PREMANUFACTURE NOTICES

The Toxic Substances Control Act (TSCA) specifies submission of some items of information on PMNs and requires the inclusion of some other items if they are available to the company that plans to manufacture a new chemical. TSCA specifies that each Premanufacture Notice (PMN) is to contain:

1. the chemical's name, identity, and molecular structure;
2. the categories or proposed categories of use for the chemical;
3. estimates of the amounts of the chemical to be made for various uses;
4. descriptions of byproducts associated with the chemical's manufacture, processing, use or disposal;
5. estimates of the numbers of workers likely to be exposed in their places of employment; and
6. information about the disposal of the substance.

In addition to those items of specified information, TSCA also requires submission of any test data about health and environmental effects of the chemical that are in the possession or control of the person submitting the notice. The general reporting requirements apply to two kinds of information: additional information about the physical-chemical properties of the new chemical and information about toxicity.

DESCRIPTION OF THE OTA STUDY PROCESS

OTA examined 740 PMNs to prepare the background paper. Six hundred and seventy of those were the total PMNs received during the first two years of the PMN program's operation from July 1979 through June 1981. The remaining 70 PMNs were those received in June 1982.

Each PMN was examined for the presence or absence of 45 items of information. For convenience, those items are grouped into 3 categories. The first category is the TSCA specified items; the second category is additional physical-chemical data, and the third category is toxicity information.

The completeness of the first category is easily measured by comparing the information reported on each PMN to the information specified in TSCA. It is impossible to make such a comparison in the cases of physical-chemical and toxicity information because TSCA does not require specific information about those properties. To provide a standard reference for measuring physical-chemical and toxicity information, OTA compared the items of information submitted on PMNs to lists of physical-chemical and toxicity tests that were developed for premarket testing of chemicals by the countries of the European Economic Community (EEC).

In 1981, EPA published lists of suggested physical-chemical and toxicity measurements to be submitted on PMNs that were identical to the EEC-required tests, the "Minimum Pre-Marketing Data" set or "MPD." However, the United States does not require submission of those data, and at a meeting of the Organization for Economic Cooperation and Development (OECD) in December 1982, the United States voted against requiring those tests as part of premarket review of chemicals in the countries that belong to the OECD.

Because TSCA does not allow EPA to require submission of any data, other than the items specified in the law, it was expected that our analysis would find that the number of data on PMN's would vary. Our results followed our expectations. Some PMN's contain every item of TSCA-specified information, additional information about physical chemical properties, and data about toxicity. Some do not contain every item of TSCA-specified information, a few contain not one additional item of physical chemical information, and almost half contained no data bearing on toxicity.

INFORMATION SUBMITTED ON PMNS THAT DESCRIBE CHEMICALS THAT HAVE ENTERED MANUFACTURE

OTA divided all the PMN's into subgroups in order to make comparisons. For instance, the letter requesting the OTA study asked whether more data were submitted on PMN's that described chemicals that have actually entered manufacture as compared to those that have not.

According to EPA records, about 50 percent of the chemicals for which PMN's were submitted during the first two years of the program had entered production by September 1982. That percentage is higher than the often-mentioned estimate that about ⅓ of all PMN's describe chemicals that have entered production. The reason for the difference is that a reasonably long time has elapsed since the PMN's in the OTA study completed review, providing more time for the completion of any steps that are required between the time of submitting the PMN and commencement of manufacture.

OTA found no difference between PMN's that described manufactured and not-yet-manufactured chemicals with respect to the frequency of submission of the TSCA-specified information. However, the reporting of both physical-chemical and toxicity data was more frequent on PMN's that described chemicals that are known to be present in commerce. Those findings are important because exposure to manufactured chemicals is certainly greater. Nevertheless, 41 percent of PMN's that described manufactured chemicals reported no toxicity data.

SUBMISSION OF INFORMATION ABOUT CHEMICALS INTENDED FOR CONSUMER USE

Chemicals intended for consumer use are of special interest because of the large number of people who may be exposed to them. Not only are there many consumers, but the chances for misuse probably increase with the number of users. Consumer-use items are purchased in retail outlets and may or may not be used according to directions. Labels and instructions may be lost, washed off, ignored, or not understood. A particularly striking example of such an occurrence was the mistaken use of a lemon-scented dishwashing detergent to flavor tea when plastic bottles of the product were mailed to consumers in 1982.

Fourteen percent (105) of the PMN's examined by OTA described chemicals that, according to the submitting companies, were intended for consumer use. There were only small differences in the frequency of submission of physical-chemical data between PMN's that described consumer-use chemicals and all other PMN's. However, toxicologic data were more frequently reported on PMN's describing consumer products.

The more frequent submission of toxicity fits with the idea that greater concern is attached to consumer-use products. Because of the potentially large number of people exposed to these products, more information about any hazard is desirable to make reasonable decisions about risk. Despite the more frequent reporting of toxicity information on the consumer use PMN's, about 40 percent reported no toxicity data.

Once a chemical completes PMN review, it goes on the Inventory of Chemical Substances and is no longer subject to regulation as a new chemical. No restrictions are imposed on the manufacture, processing, use, or disposal of substances on the Inventory. Therefore, some of the chemicals designated for non-consumer uses on PMN's may, in time, become consumer-use chemicals or be incorporated into products to which consumers may be exposed. The result is that consumers may use or be exposed to chemicals that were not reviewed as consumer-use chemicals. If that is the case, the percentage of consumer-use chemicals for which toxicity data are available to EPA, of course, decreases.

INFORMATION SUBMITTED ABOUT CHEMICALS THAT EPA IS CONSIDERING EXEMPTING FROM PMN REPORTING REQUIREMENTS

Risk assessment, when applied to chemicals, generally follows the assumption that risk is equal to some product of the hazard associated with a substance and exposure to the substance. "Hazard," in this equation, is a property of a chemical, say, its causing skin irritation or some other toxic effect. Hazard can be measured by various specific tests. "Exposure," for a new chemical is estimated by making guesses about its potential uses. For that reason, projecting industrial, commercial, or consumer uses for a new chemical is important to estimating the number of people to be exposed, the levels and routes of exposure.

Given that hazard and exposure interact in some sort of multiplicitive fashion, if either hazard or exposure is very low, it is reasonable to conclude that risk is also low. Following that reasoning, EPA has proposed exempting some groups of chemicals from PMN requirements because either hazard or exposure are judged to be low.

In particular, EPA has proposed exempting: 1) some polymers, 2) site-limited intermediates, which are chemicals synthesized and consumed in a series of reactions at one manufacturing site, and 3) chemicals to be manufactured in low volumes. Not all polymers, site-limited intermediates, or low volume substances would qualify for exemption, but many would.

The polymer exemption is premised on the idea that those substances, in general, are less likely than other chemicals to be toxic. Consistent with that idea, PMN submitters reported and evidently developed fewer toxicity data for polymers than for other classes of chemicals.

Limited exposure is associated with site-limited intermediates, which do not enter general commerce, and low production volume substances. Therefore, EPA's proposed exemptions for those chemicals incorporates the idea that the agency needs less information to make decisions about those substances because of reduced exposure.

OTA's examination of PMNs shows that toxicity information was more often submitted for site-limited intermediates than for other chemicals. Although the number of people who might be exposed to those chemicals, which generally would be used in manufacture of other chemicals, is limited, levels of exposure may be quite high. Since EPA does not require the generation of tests data, the submitting companies apparently develop toxicity information about these substances because of concern about their workers' health. Whether or not toxicity data would be developed for these substances with the same frequency if the exemption becomes final is unknown. Of course, there would be no requirement to submit the data to EPA.

PMNs describing chemicals to be made in volumes of less than 1,000 kg per year reported toxicity data more frequently than did PMNs describing other chemicals. This was a surprising finding. However, more detailed analysis showed that polymer PMNs tended to project larger production volumes. Therefore, the reduced reporting of toxicity data for polymers, which has already been noted, at least partially accounted for the less common reporting of toxicity data on high production volume chemicals.

The proposed low volume exemption would require that a complete PMN be submitted at any time the annual production volume of an exempted chemical exceeds 10,000 kg. It is of some interest, then, to estimate the frequency with which chemicals that might qualify for low volume exemption would eventually become subject to PMN review. OTA's analysis of expected increases in production volumes suggests that around a third of the low volume exemption substances will require a PMN review by their third year of production.

The proposed polymer exemption, to some extent, acknowledges the present situation. Apparently because those substances are thought to be less hazardous, fewer toxicity data are submitted about them.

The site-limited intermediate and low volume exemptions are more complex. Toxicity data are more frequently submitted on PMN's that describe those chemicals. Whether those data would be developed for the company's own use with the same frequency under an exemption policy is difficult to project. Additionally, more information on the exact nature of chemicals described in PMNs is necessary to know if submitter-identified site-limited and low volume chemicals would qualify for the proposed exemptions.

SUBMISSION OF CHRONIC TOXICITY DATA ON PMNS

TSCA singled out chemicals that may cause cancer, mutations, or birth defects, the so-called, chronic health effects, for special concern. Tests for carcinogenicity and teratogenicity (the capacity to cause birth defects) are expensive and time consuming, and only tests for mutagenicity can be expected to be carried out on chemicals before manufacture. OTA examined the frequency of the reporting of mutagenicity test results on PMNs.

Overall, 17 percent of PMNs reported mutagenicity data. As expected, the frequency of reporting of these data was higher for non-polymers (27 percent) than for polymers (7 percent). Surprisingly however, only 17 percent of non-polymer, high production volume, consumer use PMNs reported mutagenicity data.

INFORMATION SUBMITTED ON PMNS RECEIVED IN JUNE 1982

About 10 percent (70 of 740) of the PMNs examined by OTA were submitted in June 1982. The frequency of reporting of toxicity data on those PMNs was lower than the frequency on all PMNs, both those that described manufactured and not-yet-manufactured chemicals, received during the 1979 through June 1981 period.

The lower frequency of toxicity test reporting in June 1982 might be an aberration and not reflective of a downward trend. Alternatively, it might be taken as a harbinger of decreased toxicity testing during recent months. A decision can be made between these two points of view by examining PMNs received during other months.

SUMMARY OF OTA'S FINDINGS

The OTA Background Paper contains 24 tables and 9 figures of data and information. It is difficult to summarize the findings and at the same time respect the complexity of the data and the limitations inherent in a study that was restricted to an examination of the frequency of data submission. Nevertheless, some summary findings can be presented.

OTA's results place limits on possible answers to questions about how much information EPA has received on PMNs. The reporting of TSCA-specified items is high. Five of the six specified items—chemical identity, production volumes, uses for the chemical, numbers of workers likely to be exposed in their places of employment, and disposal methods—were reported on about 90 percent of all PMNs. The sixth specified item, information about byproducts generated in the manufacture of the chemical, was reported on about two-thirds of all PMNs.

Ninety-six percent of all PMNs reported at least one item of non-TSCA specified physical chemical information. Fifty-three percent reported at least one toxicity test result.

Therefore, the majority of all PMNs contain every TSCA-specified item and at least one item of physical-chemical information, and about half report at least one item of toxicity information. Turned around, of course, the previous statement says that not all PMNs report even the TSCA-specified items, and almost half report not one item of toxicity information. Furthermore, only 17 percent of PMNs have any test information about the likelihood of a substance causing cancer, birth defects, or mutations—three effects that were singled out for special concern in TSCA. Even fewer, about 10 percent, report any information from tests that estimate environmental effects.

OTA's examination of subgroups of PMNs found more frequent reporting of information on PMNs that are more likely to present risks. For instance, reporting of both physical-chemical and toxicity data was more frequent on PMNs that described chemicals that are now being manufactured. Toxicity information was more frequently reported on PMNs that described nonpolymeric substances. That seems especially welcome because hazard is more often associated with nonpolymeric substances, and toxicity data greatly aid EPA in its difficult task of making decisions about risk. Additionally, toxicity data are more frequently submitted on PMNs that describe chemicals intended for consumer use. That is also encouraging because of the widespread exposure that is associated with consumer products.

Regardless of how the information about the frequency of submission of data is interpreted, immediate questions arise about whether the information available for a particular substance is appropriate and sufficient. Answering those questions would require an examination of EPA's decisionmaking process about some PMNs on a case-by-case basis. That study would be different from the one done by OTA, and would involve a process similar, in some regards, to that used by EPA to review PMNs. A group of scientists would review the data on a group of PMNs, supplement that information with other information available from the scientific literature and experts, decide if EPA's decisions were appropriate, and ask whether additional information on the PMN would have made a difference in the decisions.

In the meantime, OTA's findings about some trends in reporting information on PMNs are encouraging. For instance, the generally higher frequency of reporting of toxicity data on substances that are more likely to be hazards is encouraging. At the same time, many PMNs contain no toxicity information, and that finding must cause reservations to be attached to any conclusions about whether the information now reported is adequate for the review of all new chemicals.

Thank you.

TESTIMONY OF
DR. J. CLARENCE DAVIES
EXECUTIVE VICE PRESIDENT
THE CONSERVATION FOUNDATION
BEFORE THE
SUBCOMMITTEE ON TOXIC SUBSTANCES
AND ENVIRONMENTAL OVERSIGHT
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

JULY 29, 1983

I appreciate being given the opportunity to appear before you to discuss the Toxic Substances Control Act. I was responsible, in 1970, for the original draft of what later became TSCA, and I have followed closely the implementation of the act since its passage in 1976.

TSCA can be and should be one of the most important environmental laws on the books. Although it has sometimes been referred to as a "gap-filler," designed to supplement the other environmental statutes, this description understates the intent and potential of the act. If TSCA is not being adequately implemented--and it is not--then the whole range of institutional and legal mechanisms we have established to protect the public from unreasonable risks from chemicals is flawed and vulnerable.

TSCA has three basic purposes. First, it is designed to obtain the information necessary to determine the degree of risk posed by particular chemicals or groups of chemicals. This is the purpose of Section 4 of the act, which authorizes EPA to require testing of particular chemicals; of the various authorities in Section 8, which allow EPA to obtain relevant information from chemical manufacturers and processors; and of some parts of Section 5, the section which relates to new chemicals. No other federal health or safety statute contains as strong or as comprehensive a set of authorities for obtaining information about risk, and such information is essential for intelligent and balanced regulatory decisions.

The second purpose of TSCA is to prevent unreasonable risks from occurring. This is the rationale for Section 5 of the act. Although we have applied a preventive approach to particular kinds of chemicals, notably drugs and pesticides, TSCA is the only general environmental statute that allows the government to deal with problems before people are hurt and before industry has made a major economic investment. TSCA's autorities relating to new chemicals are the major hope we have of making real long-term progess in controlling unreasonable risks. If these authorities are not adequately implemented we will constantly face new problems, and the toxic-substance-of-the-month syndrome will continue indefinitely.

The third purpose that TSCA serves is to deal with existing unreasonable risks. The provisions for doing this are contained in Section 6. Although the Clean Air Act, the Clean Water Act, and other laws are appropriate for dealing with many types of pollution problems, they are increasingly cumbersome and inappropriate for dealing with the new generation of toxic pollutants. This new generation of pollutants is not limited to one particular medium or one particular use, but, like asbestos and PCB's, is found in all segments of the environment, and is readily transferable, both through natural processes and human actions, from one segment to another. TSCA is uniquely suited to deal with this kind of problem.

Testing (Section 4)

The reality of TSCA implementation has not matched the act's potential. EPA is not getting the information needed about existing chemicals, it is not adequately reviewing new chemicals, and it has done very little to regulate the risks that already exist. Let me try to describe some of the implementation problems and suggest in broad terms what might be done to solve them.

TSCA Section 4 authorizes the EPA administrator to promulgate a rule requiring the manufacturers of a chemical or group of chemicals to conduct tests to determine the health or environmental effects of the chemical. To date, not one final testing rule has been issued. Although the lack of information about the effects of chemicals is generally agreed to be a major problem, the most important legal tool the government has to obtain this information remains essentially unused.

Several test rules have been proposed. Also, in the past two years EPA has encouraged voluntary testing by the chemical industry as a substitute for Section 4 rules, The agency's reason for encouraging voluntary testing is the length of time it takes to issue a rule. Voluntary testing has both advantages and disadvantages, but it is surely worth exploring whether a more efficient method for requiring testing can be found. One way to do this would be to allow the EPA Administrator to issue testing requirements by order rather than by a rule.

Another problem with Section 4 relates to the process of choosing which chemicals to test. TSCA established an Interagency Testing Committee which is charged with recommending chemicals to EPA for testing. EPA is required to respond to the committee's recommendations within 12 months. EPA's response in about half the cases of recommended chemicals has been to decide that testing is not needed.

If for approximately half of the chemicals that the interagency committee says need testing the EPA concludes that no testing is necessary, either the committee is not doing a good job of nominating chemicals or EPA is not giving adequate weight to the committee's recommendations. Both explanations have some validity, but the primary need is to improve the quality of the committee's recommendations by giving the committee access to information that it now lacks. The way the process currently works, industry data about chemicals being considered by the committee are not made available until after the committee has made a final decision. Thus the committee may not know about testing that the industry has done or it may not realize that production of a particular chemical has ceased. It would be to the advantage of all parties if this kind of information, readily available through use of Sections 8(a) and 8(d) of TSCA, were given to the interagency committee before it made its final recommendations to EPA.

New Chemicals (Section 5)

The most important shortcoming in TSCA implementation is the inadequacy of the information submitted in the premanufacturing notifications for new chemicals. The purpose of the premanufacturing notification is to allow EPA to make a "reasoned evaluation of the health and environmental effects" of a new chemical. On a large number of the most important new chemicals, EPA is not getting the information it needs to make such an evaluation. It is failing to meet its responsibility to see that new problems are not created as fast as the old ones are solved.

EPA and the chemical industry have offered two kinds of defenses of the existing system for reviewing new chemicals. It is conceded by all sides that the new chemical notifications lack data on health and environmental effects. But, says one line of defense, such data are not needed for most chemicals--either the chemical is produced only in small volumes, or there is no exposure to the general public, or the chemical is a polymer and thus poses little risk. However, the recent study by the Office of Technology Assessment of the new chemical review process found that 83 percent of the notifications for high-volume, consumer-use, non-polymer chemicals contained no data at all about chronic toxicity. In other words, the great majority of notifications for the chemicals most likely to create unreasonable risks contained no information about the risks which are of most concern. The OTA study also found that 38 percent of the notifications did not contain even the elementary data explicitly required by the act, such as the amount of exposure to workers or whether any byproducts are created in the production process.

The defense of this abysmal situation that has been made by EPA is that the agency does not need effects data on most new chemicals because it can determine the degree of risk by looking at other analogous chemicals, the so-called "structure-activity relationship" (SAR) approach. There are two problems with this approach. First, the act makes it quite clear that the burden should be on the manufacturer to provide relevant data, not on EPA. The agency is using its scarce resources for a task which it should not have to undertake. The second problem is that the SAR approach probably is not valid for many, maybe even most chemicals. I do not know any toxicologist who believes that SAR analysis is an adequate substitute for test data on health and environmental effects.

As a historical note, when TSCA was being formulated in Congress one of the most frequent industry arguments against the premanufacture notification requirement was that all companies adequately tested new chemicals as a matter of routine, and therefore no regulatory requirements were needed. It now seems clear that testing for chronic health effects and for environmental effects is anything but routine--it is a rarity.

There are several ways in which adequate information on new chemicals could be assured. The Europeans have adopted the most direct approach which is simply to list a set of tests which must be performed for each new chemical unless there are persuasive scientific reasons for not doing a particular test. Because of various differences between the European legislation and TSCA, the European approach should not be directly adopted here. But a combination of testing guidelines enforced through Section 5(e) of TSCA, modification of the wording of Section 5(e) (which allows EPA to reqire more data under certain conditions), and exemptions for categories of low-risk chemicals would provide a workable system for obtaining data on the effects of a chemical. Alternatively, EPA could designate categories of potentially high-risk chemicals and promulgate a set of data requirements for those categories.

Another set of problems with the implementation of Section 5 relates to the provisions for following-up on new chemical notifications. The act wisely recognized that a chemical which might not pose a significant risk when first manufactured could pose a risk at some later date. A chemical originally manufactured just for closed-system use within industry might later be used in consumer products. Or a chemical originally produced in very small quantities might later be produced in large volumes. To deal with these types of changes, which are quite common, the act provided for EPA to issue "significant new use rules," which would require manufacturers of chemicals covered by the rule to submit a new notification if the chemical were to be put to a significant new use. What constitutes a significant new use must be spelled out for each chemical by the rule.

As in the case of Section 4 testing rules, not a single significant new use rule has become final in the seven years since the act was passed. However, during the past year EPA's Office of Toxic Substances has been giving serious thought to a follow-up strategy for new chemicals. Three significant new use rules have been proposed in the past six months. There is some hope that at least this part of the act will be seriously implemented.

Existing Unreasonable Risks (Section 6)

Aside from regulating PCB's, which was required by the statute, almost no actions of consequence have been taken under TSCA Section 6 to regulate existing chemical risks. Aerosol uses of CFCs, roadside dumping of dioxin, and a reporting rule for asbestos in schools are the only other actions which have been taken.

It can be argued that so few Section 6 actions have been taken because so few unreasonable risks exist. In part, obviously, this depends on one's definition of "unreasonable." I would argue that we are still exposed to what I would consider unreasonable risks--some uses of asbestos, and the use of formaldehyde as a major component of hair lotions, to name just a couple--and that therefore one must seek other explanations for the fact that Section 6 has been used so rarely.

The underlying reason Section 6 has not been used more often is that EPA really has not developed a coherent strategy for dealing with the toxic substances problem. It has not faced-up to the fact that dealing with toxics under the older medium-specific laws all too often results in the problem simply being shifted from one part of the environment to another. If a coherent strategy were developed I think that TSCA Section 6 logically should be a key part of it. However, there is no indication that the agency is even thinking along these lines, much less taking any action.

Should TSCA Be Amended?

There has been a basic acceptance of the need for TSCA. The chemical industry, to its credit, has accepted that there is a governmental and public role in examining new chemicals and in ensuring that chemicals now on the market do not pose unreasonable risks. There is a consensus that the basic purposes and framework of TSCA are valid and necessary.

There is not a consensus about how the act has been implemented. However, in the face of no testing rules, no significant new use rules, almost no Section 6 rules, and blatantly inadequate information submitted on new chemicals, it seems to me obvious that TSCA implementation has been less than satisfactory. Neither the Congress nor the American public are getting the information and the protection that they expected when the act was passed.

The language of the statute is generally flexible, although many of its procedural aspects are unnecessarily cumbersome. At least in theory, adequate authority exists in the act to undertake almost any action necessary to deal with chemical risks. But if these authorities have not been exercised by two administrations over a period of seven years something needs to change. The most direct and effective way for Congress to get what it thought it was getting in 1976 is to amend the statute to make the congressional intent crystal clear and to remove some of the procedural difficulties that the act contains.

It is vitally important that TSCA be adequately implemented. The problem of toxic chemicals is serious, and we are still in the early stages of discovering its true dimensions. TSCA is potentially the best tool we have for dealing with the problems and for getting the information to separate unreasonable risks from tolerable ones. Whether its potential will be realized depends heavily on the actions of your committee.

# # #

A Perspective on the Toxic Substances Control Act

Statement of
Jeremiah J. Kenney, Jr.
Director of Federal Affairs, Union Carbide Corporation

Before the Subcommittee on
Toxic Substances and Environmental Oversight
of the
Committee on Environment and Public Works
United States Senate

July 29, 1983

Mr. Chairman and Members of the Committee. I am Jeremiah J. Kenney, Jr. and I am Director of Federal Affairs for Union Carbide Corporation, which is a large manufacturer of chemicals and plastics and many other products which are chemical substances as defined in the Toxic Substances Control Act. I am pleased to respond to the invitation of this Committee to provide some observations on how the Act is working.*

I. History and Background of the Statute

As you are aware, the concepts for a Toxic Substances Control Act were first revealed by the President's Council on Environmental Quality in 1970, when it was chaired by Russell Train and staffed by Terry Davies. The legislation was proposed to Congress in 1971 as part of the legislative program of the Nixon Administration. An April, 1971, Report of the Council, entitled Toxic Substances, provided the rationale for the proposal, and it cited a number of concerns involving various metals and synthetic organic compounds, including lead, cadmium, mercury, NTA, PCB's and ONCB. Other substances of concern at the time included asbestos and vinyl chloride monomer.

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* This testimony is based upon personal experience representing Union Carbide in Washington and from an active involvement, from the industry side of the table, during all the time this statute was under consideration by the Congress, and since. I do not have any direct responsibility for any of Union Carbide's programs for complying with the Toxic Substances Control Act.

A revised bill, drafted by the Senate Commerce Committee, passed the Senate unanimously in May of 1972. A significantly different bill passed the House on October 13, 1972, but it was so late in the session that the Congress adjourned before a conference could be held.

The process repeated itself during the 93rd Congress. Both the Senate and the House passed legislation, but were unable to reach agreement in a conference committee and the bill died when Congress adjourned in 1974.

A major cause of this legislative stalemate was controversy over the proper scope of federal control over industrial chemicals. For nearly four years, Congress searched for a legislative approach that would afford adequate protection to human health and the environment while preserving an innovative and dynamic chemical industry.

The 94th Congress succeeded where its predecessors had not, and a Toxic Substances Control Act was passed by the Congress and signed into law by President Ford on October 12, 1976.

As frustrating as the process was, it had good points. The concepts and the language of the Toxic Substances Control Act were intensively considered and reviewed -- three times by the Senate Commerce Committee, three times by the House Committee on Energy and Commerce and its subcommittee, and by a conference committee. Its provisions were refined and honed over six years by many talented members of the House and Senate, by the efforts of many skilled persons on Congressional staffs, and by a lot of input from the Administration, environmental groups and business organizations. In the end, the bill had a broad spectrum of informed support across all the areas of our society with an interest in its provisions.

II. The Nature of the Act

There are several characteristics of the Act that deserve special mention in light of this legislative history.

1. It is a broad statute. Its provisions are basically applicable to all matter; its definition of "chemical substance" is all encompassing; and the exemptions in the statute are narrow and limited, serving as much to broaden its scope as to confine it.

2. The authority conferred by the statute is as comprehensive as it is broad; as deep as it is wide. It covers the manufacture, distribution in commerce, processing, use, or disposal of chemical substances, or mixtures in some instances whenever or wherever they present an unreasonable risk of injury to health or the environment. The remedies available to EPA are equally broad. It, in the ultimate, can do almost anything from slapping a company on the wrist to putting it out of business, if the courts approve. Two other aspects of the law flow from these facts. First, there are significant elements of due process woven into the statute, in response to the constitutional requirements. Second, the Toxic Substances Control Act is basically designed and intended as a gap-filling, back-stop measure intended to be invoked when other measures and statutes are ineffective.

3. The statute is complex. But the environment is complex. The chemical industry is complex, and the problems of toxicology are complex. But to say that the statute is complex is not to say that it is disorderly or inchoate. There is a sound logic and a sensible symmetry

to its provisions. It may be worth noting that during all of its years of consideration in both the House and Senate, no member of Congress stepped up to offer an easier or simpler way.

4. For the environment the statute provides what might be called a "defense in depth" (though some of my colleagues in industry might view it as double or triple jeopardy). A new chemical substance can make its way through the premanufacturing notice procedure, only to be faced later with testing requirements under the provisions of Section 4, new use restrictions under Section 5, and potential extinction under Sections 6 or 7. Except for the premanufacturing notice provisions, any existing chemical can face the gamut. No chemical substance is ever "home free" and this is the way it should be.

5. The statute is flexible. It grants wide areas of discretion to the Administrator of EPA. This discretion is seldom absolute. The committees which drafted TSCA spent a lot of time, talent and energy in crafting careful guidelines and criteria. Nevertheless, the Congress determined, wisely, in my view, that the breadth, complexity and variety of the problems likely to arise under the statute could only be dealt with by conferring a great deal of discretion to the informed expertise of the agency.

This is well illustrated by the provisions of Section 5 dealing with premanufacturing notices and the present controversy about the amount of testing and the adequacy of data with respect to new chemical substances.

I would like to outline some of the considerations that went into the final legislative product in this area.

A. Most new chemicals do not involve new chemistry. They are minor modifications of existing chemicals. Most chemical producers operate within narrow bands of chemistry, in areas where they have expertise and experience. Most new chemical substances, as defined in TSCA, do not present novel environmental problems; their effects can readily be predicted from what is already known about similar, closely related substances. There is little to gain in testing for knowledge that is already at hand.

B. Most new chemicals cannot stand the costs of extensive testing -- and certainly not before their producers know whether or not they will ever succeed in a dynamic, highly competitive and constantly changing market.

C. Significant volumes of the production of many chemical producers, including Union Carbide, are intermediate chemicals -- used only for the production of other products. Many of these are on-site intermediates -- used within the same plant -- for production of something else. In many instances, the process is totally enclosed -- no environmental exposure at all. In this sense, products and their uses move up the scale to off-site intermediates, chemicals with industrial or process uses, where the environmental exposure is confined to a plant site, and ultimately to chemical substances that are sold in grocery stores. The variety is almost endless. The need for new toxicology testing cannot be prescribed by formula. It has to be a matter of informed judgement.

D. Testing is sometimes hard to do accurately. Tests will sometimes produce false negative, or false positive results. Test animals do not always react the way humans would. Some substances are more toxic to humans than to test animals and some are less. We know that many people are repelled by tests on helpless animals.

E. Some chemicals are so reactive or unstable that they cannot be tested. They may react with air, water, or the moisture in a rabbit's eye or a rodent's belly. If the chemical substances produced by that reaction are ones whose toxicology is well-known, then there is no mystery and no need for further testing.

F. Structure activity relationships can be a powerful tool for determining the toxicology of many with related structures, especially when they are members of well-tested classes. In these cases, additional tests are needless and wasteful.

If we look at the results, I believe the answer is reassuring. None of the studies of the process to date have charged that the process is not working. While many questions have been raised about the adequacy of data there is no evidence, no examples, of where the system has failed, and not one shred of evidence to indicate that the statute is deficient.

III. Reactions to the Statute

Let me now turn to some of the reactions to the bill and to its effects.

1. Some envirohmentalists, quite understandably, are disappointed. For the sake of my point, let me overstate the view by saying that some environmentalists see TSCA as the only thing standing between a rapacious chemical industry and a helpless environment. They tend to forget the dozen or more other statutes that come into play, including the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, FIFRA, FDCA, the CPSC, etcetera. But more important, they often totally overlook several other powerful factors that have a great influence.

Concern over product liability suits imposes pervasive constraints on the chemical industry. The hazardous material transportation regulations of the U.S. Department of Transportation are a major consideration. Why make it if you can't ship it? Our customers play a major role. They want to know the health and environmental effects of what they buy in order to protect themselves, their employees and their customers, and if they don't find out from us they will buy from one of our competitors. And, of course, the people in the chemical industry also have a sense of morality.

2. Some critics of the Act, I regret to say, seem to have a body-count mentality. A few want to notch the handle of their six-shooter for chemicals that have bitten the dust. They want the scalps of chemical industry executives dangling from their belts. They are disappointed that this hasn't happened. They forget that chemical producers have strong motives to make sure it does not happen. The chemical substance which is challenged by EPA is likely to have a hard time in the marketplace. Tests mandated by EPA will take longer (because of administrative lead-time) than tests voluntarily undertaken. The costs of filing an ineffective PMN are likely to exceed the costs of doing it right the first time. And industry executives don't relish losing their scalps to anyone. In point of fact, the statute is designed to rely on discussion, negotiation and conciliation rather than on adversarial confrontation. It works better that way.

3. From the industry viewpoint, living under TSCA is not as bad as some thought it would be. No one's worst fears have yet materialized. For responsible chemical companies, the enactment of the statute caused evolutionary, not revolutionary, changes in the way they did things. Toxicology testing, where indicated, had been a routine procedure for many years. The law, for most, only accelerated the trends.

The industry reaction is not unified. This is a large, diverse, and highly competitive industry. Unanimity is hard to find. The reaction to

TSCA is likely to vary within a single company. The research chemist whose "brilliant" new product is shot down internally because it is too toxic or because the potential market will not support the testing costs is convinced that TSCA inhibits innovation. From that viewpont, he is correct. The product manager who has to pay for the costs of preparing the PMN and the costs of tests may think it a lot of meddlesome red tape. The corporate environmental managers are pleased to have statutory support for their efforts. Significant changes in company procedures and staffing have occurred as a direct or indirect result of TSCA requirements. The chemical industry accepts the law as consistent with the public need for effective environmental measures and is committed to living up to it.

While there may be exceptions, I find that industry people who are involved have a considerable (albeit sometimes reluctant) respect for the professionalism and competence of the majority of the people at EPA who are involved in the TSCA program. And in saying this, I also want to say that I have yet to find someone in the industry who believes the people of the agency are pushovers for the industry point of view. It is significant that there has not yet been a single legal challenge to any of the orders issued by the Administrator under Section 5(e) of TSCA. And there is great respect for, and understanding of, the fact that the agency keeps a big club in the closet, available for use whenever necessary.

V. Conclusions

In my view, the statute has stood the test of time very well. None of the responsible administrators at EPA, over two administrations, has complained about lack of authority or even recommended any significant changes in the law.

I continue to believe, on the basis of all the evidence I've seen, that the statute is effective, useful and working in the public interest.

That does not mean the absence of controversy. Chemical companies and others affected by EPA administration, interpretation and application of the statute often object that the agency is over-reaching, and over-reacting. Environmental groups complain that it is not doing enough. That is the way it should be. It leaves the agency in the uncomfortable, but thoroughly tenable position of being about mid-way between the extremes.

I will be glad to try to respond to any questions.

* * *

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UNION CARBIDE CORPORATION 1100 FIFTEENTH STREET, N.W., WASHINGTON, DC 20005
FEDERAL GOVERNMENT RELATIONS
PHONE (202) 872-8555

JEREMIAH J. KENNEY, JR.
DIRECTOR Federal Affairs

November 9, 1983

The Honorable
Dave Durenberger
Chairman
Subcommittee on Toxic Substances
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Senator Durenberger:

In response to your letter of October 5, I am enclosing my answers to the series of follow-up questions which resulted from the Subcommittee's recent hearing on toxic substances.

I hope my comments will be helpful to you and the Members of the Subcommittee. If I can be of further assistance in any way, please let me know.

Sincerely,

Jerry Kenney

Jeremiah J. Kenney, Jr.

cc: Mr. Ronald Outen, Professional Staff
Committee on Environment and Public Works
United States Senate

/jr/#2544A

Responses of Jeremiah J. Kenney, Jr., Union Carbide Corporation

to the Questions Posed

by the Senate Committee on Environment and Public Works

1. Question: When Congress enacted TSCA it was concerned that required testing might overwhelm available testing capacity.

- Did your company expand its laboratory testing capacity and budget for testing at the time TSCA was enacted?
- If so, has that capacity been fully utilized?
- Do you have any information or impressions about the extent to which the testing capacity of independent laboratories is being utilized at the present time?

Answer: Union Carbide had maintained its own toxicology testing capability, operated in association with Carnegie-Mellon University, since the mid-1930's, so the enactment of TSCA in 1976 did not require a major change in the Corporation's approach to testing. However, since its enactment, the Corporation has increased the capacity of its toxicology testing laboratory by approximately 25 percent. During this period we have also invested substantial sums of money in a continual modernization and updating of the facilities and equipment to assure that they are at the "state of the art." In addition, Union Carbide was a founding member of the Chemical Industry Institute of Toxicology (CIIT) and has devoted substantial sums to the testing programs at the Institute. A significant number of the testing programs at the Institute have involved products which are manufactured by Union Carbide.

It is my impression that the testing capacity of independent laboratories is not fully utilized at this time, and our own laboratory has some excess capacity. One of the major factors here has been the effect of the economic recession on the chemical industry, but it is clear that the need for testing facilities has not grown as rapidly as many expected when TSCA was enacted.

2. Question: Please provide the following information about your company's experience with TSCA requirements:

(a) How many PMN's have you filed?

(i) of these, how many have been subjected to "detailed review" by EPA?

(ii) How many have you subsequently withdrawn because of EPA's concern about the chemical?

(iii) How many have been the subject of an EPA request for additional information beyond that you originally submitted?

(iv) In how many cases have you performed additional tests at EPA's request after the date of original submittal?

(b) How many section 8(d) notices have you filed?

(c) How many section 8(e) notices have you filed?

Answer: The submission of Pre-Manufacture Notices (PMN) became effective in 1979. From then through October 4, 1983, Union Carbide has submitted 42 PMNs, of which one was voided because the substance was already on the inventory and one withdrawn because it was determined to be covered by a PMN we had previously submitted. Except for those still pending, none have been withdrawn because of EPA concerns about the chemical. Several have, however, been subject to informal requests from EPA for additional information. Except for those still pending, all Union Carbide's PMNs have been cleared without any restrictive orders. In no case have we performed additional tests at EPA's request after the original submission. Six of our PMNs involved site-limited intermediates and fourteen were polymers. In connection with these 42 PMNs, Union Carbide submitted data from more than 200 tests, but such a "box-score" does not provide meaningful information as to whether our testing was excessive, appropriate, or adequate.

In response to the EPA requests for data and tests under Section 8(d), Union Carbide has submitted 58 health and safety studies which had not previously been published on 30 chemicals through October, 1983. The bulk of these studies had not previously been published because the results were not well suited to publication in technical journals, because peer review had not been sought or completed, or the actual write-up not finished. None of these reports were withheld because of confidentiality and the results have, in fact, been utilized in our reviews of toxicology, in the preparation of material data safety sheets, product labels and in other appropriate ways.

In terms of Section 8(e), requiring submission of notices of substantial risk, Union Carbide has submitted 16 notices to EPA on 13 chemicals, and in almost every case, supplemental reports have been submitted as further information was developed.

3. Question: EPA's testimony stated that TSCA regulatory authority under section 6 applies "only if actions under other laws or by other Federal agencies are not forthcoming."

It also stated in section 9 of TSCA "Congress directed EPA ... to defer action to other laws when authority to take action exists elsewhere." Do you agree with EPA's interpretation of the requirements of section 9?

Answer: I am not fully familiar with the details of EPA's interpretation of the requirements of Section 9, and their interaction with Section 6, and so I am unable to say whether or not I agree. I have always regarded TSCA as gap-filling legislation and believe that the provisions of Section 6 and Section 9 appropriately require the Admiistrator to "defer" first to the authority of other agencies and then to his other first-line authorities (like the Clean Air and Clean Water Acts) before invoking the regulatory authority of TSCA. In this context, "defer" does not mean to put off action or to delay, but rather to accord deference -- "a respectful and courteous regard" for the first-line authority in other statutes, and the language in Sections 6 and 9 spell out in some detail the terms of this deference.

4. Question: One of the concepts behind the enactment of TSCA was that its various information gathering authorities, including test rules and the reporting authorities in section 8, could be used to support other programs in EPA and even in other agencies.

- Do you think that TSCA can be used in this way?
- Has EPA made adequate use of these authorities?
- If you think TSCA could be used more effectively in this way, please be specific about how particular provisions of TSCA could be used.

Answer: Yes, I believe that the information-gathering authorities of TSCA can be used to support other programs in EPA and even other agencies, as long as they comply with the statutory requirements in TSCA.

There is also some evidence that other agencies of Government would rather "do their own thing" than use data available to EPA. It seems to me that each Department or Agency of the Federal Government should routinely review the information already available at EPA as a result of TSCA, and make use of that data, instead of initiating new actions requiring firms to resubmit extensive data. For instance, Union Carbide and others have had to submit to OSHA, for its purposes, data that had already been submitted to EPA under Section 8.

We have also had some experience which indicates that other research agencies of the Federal Government, because they are technically not covered by the mandatory reporting provisions of Section 8(e), fail to report significant health and safety information to EPA.

5. Question: Many PMN's are submitted with most of the information claimed as confidential business information. Information in section 8(e) notices is often claimed confidential as well. EPA has testified that the Agency does not review a claim of confidentiality except in response to a request for information filed under the Freedom of Information Act.

- Do you feel that present practices and procedures allow for adequate public oversight of EPA decisions?
- What kinds of information do you feel should be routinely held confidential to protect the manufacturer, and what information should be released to the public?
- Under what circumstances would it be approriate for a company to claim as confidential the name of a chemical that has been implicated in causing a serious toxic effect?

Answer: In my view, the present practices and procedures of EPA with respect to confidentiality in PMNs claims strike a reasonable balance between the desirability for public knowledge and participation with the commercial needs for the protection of confidential business information. This protection is highly important because the chemical industry is "information" oriented in that each company tends to have a great deal of valuable data and information which deserves protection against disclosure to its numerous and aggressive competitors, both in the U.S. and elsewhere in the world.

A full discussion of the kinds of information which should be held confidential, and the kinds which should be made public would occupy more time and space than is appropriate here. It should be noted, however, the Section 14 of TSCA specifically authorizes the Administrator to disclose confidential information if he determines that the disclosure is necessary to protect the health or the environment against an unreasonable risk of injury.

While there can be good business reasons for keeping the identity of a substance confidential, the provisions of Section 14 specifically and properly make the results of most health and safety studies available to the public. Both the public and the Agency can effectively react to health data on chemical "X" without knowing its identity.

It seems to me that competitive business circumstances can exist which would justify a confidentiality claim for the name of the chemical in a PMN, even if the chemical has been implicated in causing a serious toxic effect. However, I do have some difficulty in seeing how a chemical that has never been manufactured can be implicated in this way, and I think that the Administrator of EPA has enough power, under the statute, and enough regard for the public interest to respond appropriately to such an implication.

6. Question: I assume you are familiar with the array of toxicity tests known as "Minimum Premarket Data", or MPD, that was developed by the OECD (copy attached). Let us assume that you had, for a particular chemical, good data from each type test listed in the MPD. Please rate as "good", "fair", "poor", or "not possible", the predictive ability of this set of data in terms of the potential for human toxicity of each of the following types: neurotoxicity, behavioral abnormalities, cancer, birth defects, gene defects, reproductive dysfunction, sublethal metabolic dysfunction, acute effects of various types.

Please explain whether and how your company assesses explicitly the toxicity of a new chemical for each of these effects before it is marketed. Is there an official in your company who is required to sign off on the safety of a new chemical before it can be marketed?

Answer: I am not qualified to answer that question personally, and my colleagues at Union Carbide indicate that a full answer from them would be lengthy and complex. They also indicate that their answer is not likely to differ significantly from the responses which we expect the Committee to receive from its other witnesses who received this question. However, if the Committee is still desirous of securing Union Carbide's views, please let me know and we will go to work on it.

Union Carbide does assess the toxicity and exposure of a new chemical for the effects listed in this question before it is marketed, but this assessment does not necessarily involve the generation of test data, and the details of the assessment vary depending on the type of new chemical (i.e., whether it is a polymer, or site-limited intermediate), the nature of human and environmental exposure, and other pertinent factors. Union Carbide's Director of Health, Safety and the Environment is required to sign off on every new PMN we submit.

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November 8, 1983

STATEMENT BY
THE NEW JERSEY SCHOOL BOARDS ASSOCIATION
BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT

July 29, 1983

Subject: The Problem of Asbestos
in New Jersey's Schools

Presented by: Jerrothia Riggs
President
Camden City Board of Education
Camden, New Jersey

CHAIRMAN DURENBERGER, MEMBERS OF THE SUBCOMMITTEE, LADIES AND GENTLEMEN. MY NAME IS JERROTHIA RIGGS AND I AM THE PRESIDENT OF THE BOARD OF EDUCATION IN CAMDEN, NEW JERSEY. I HAVE BEEN ASKED TO TESTIFY ON THE PROBLEM OF ASBESTOS AS A REPRESENTATIVE OF AN URBAN DISTRICT WHICH HAS A SEVERE PROBLEM WITH ASBESTOS IN ITS SCHOOLS. I HAVE WITH ME OCTAVIUS T. REID, JR., DEPUTY EXECUTIVE DIRECTOR OF THE NEW JERSEY SCHOOL BOARDS ASSOCIATION.

BEFORE I OUTLINE THE PROBLEM IN CAMDEN, I WOULD LIKE TO PRESENT AN OVERVIEW OF THE PROBLEM STATEWIDE AS PREPARED BY THE NEW JERSEY SCHOOL BOARDS ASSOCIATION WHICH REPRESENTS THE 611 BOARDS OF EDUCATION IN OUR STATE.

ASBESTOS IS A COMMON TERM THAT MOST PEOPLE IDENTIFY AS A MATERIAL WHICH IS CHEAP AND EFFECTIVE FOR A WIDE VARIETY OF BUILDING APPLICATIONS. FOR A CONSIDERABLE NUMBER OF YEARS, IT WAS USED EXTENSIVELY IN THE CONSTRUCTION INDUSTRY, DUE IN LARGE PART TO ITS LOW COST, ITS EASY ACCESSIBILITY, ITS SUPERIOR FIRE RETARDANT ABILITIES, AND ITS LIGHT WEIGHT. TODAY, IT THREATENS TO VIE FOR THE TITLE OF "THE NATION'S NUMBER ONE CHEMICAL KILLER." ITS PRESENCE HAS CAUSED EVERYTHING FROM PANIC AND ALARM TO CAUTION, APPREHENSION AND STUDIED CONCERN. DURING THE PAST DECADE, THERE HAS BEEN SUBSTANTIAL ATTENTION PAID TO THE PROBLEMS OF ASBESTOS CONTAMINATION AND ITS POTENTIALLY HARMFUL EFFECTS ON THOSE WHO COME INTO CONTACT WITH IT.

ASBESTOS IS VIRTUALLY EVERYWHERE. IT IS A WIDE-SPREAD ENVIRONMENTAL CONTAMINANT FOR A MAJOR PORTION OF OUR SOCIETY. OUR CONCERN HERE TODAY, OF COURSE, IS THE POTENTIAL EFFECT OF ASBESTOS CONTAMINATION ON THOSE WHO ARE UNDER OUR CHARGE -- THAT IS, THE CHILDREN OF OUR STATE'S SCHOOLS AND THE EMPLOYEES, STAFF, PARENTS, AND ALL OF THE PUBLIC WHO ENTER OUR BUILDINGS.

ASBESTOS HAS BEEN USED EXTENSIVELY IN THE PUBLIC SCHOOLS SINCE 1946 FOR FIREPROOFING, INSULATION, AS WELL AS DECORATION. BY ITS VERY NATURE, DUE TO ITS SIZE, FORM, AND AERODYNAMIC QUALITIES, ASBESTOS IS A MATERIAL WHICH EXISTS IN VERY LOW CONCENTRATIONS AND REMAINS AIRBORNE IN AREAS OCCUPIED BY HUMANS. THIS IS OF VERY SPECIAL CONCERN BECAUSE OVER THE PAST DECADE SOCIETY HAS BECOME MORE AWARE OF THE FACT THAT ABESTOS FIBERS, EVEN IN EXTREMELY LOW CONCENTRATIONS, ARE POTENTIALLY CARCINOGENIC. THEY CAN HAVE A POTENTIALLY NEGATIVE BIOLOGICAL EFFECT ON THE HUMAN BODY THAT PERSISTS FOR DECADES BEFORE IT IS EVEN DISCOVERED AND CAN CAUSE SEVERE HARM OR DEATH TO EXPOSED INDIVIDUALS.

AS YOU ARE PROBABLY AWARE, IN 1973 THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY ISSUED A BAN ON THE USE OF SPRAYED ASBESTOS BECAUSE OF ITS THREAT TO HUMAN HEALTH. THIS BAN CAME ABOUT AFTER SOME RESEARCH WHICH SHOWED A CORRELATION BETWEEN THE SHIPYARD WORKERS WHO HAD HANDLED ASBESTOS DURING WORLD WAR II AND THE INCIDENCE OF CANCER AS A RESULT OF THAT EXPOSURE. FURTHER RESEARCH IDENTIFIED THE CANCER OF THESE WORKERS AS A MESOTHELIOMA, A RATHER SPECIFIC FORM OF CANCER DIRECTLY RELATED TO ASBESTOS EXPSOSURE.

ASBESTOS IN THE SCHOOL ENVIRONMENT PRESENTS SPECIAL CONCERNS FOR CHILDREN. THIS POPULATION DIFFERS FROM OTHER NON-OCCUPATIONAL GROUPS IN BOTH AGE AND BEHAVIOR. THE EXPOSURE OF CHILDREN EARLY IN LIFE TO ASBESTOS IN SCHOOL BUILDINGS PROVIDES A LONG DEVELOPMENTAL PERIOD FOR ASBESTOS-RELATED DISEASES. ONE OF THE THINGS THAT WE ALREADY KNOW FROM EXISTING RESEARCH ABOUT ASBESTOS IS THAT IT SOMETIMES TAKES AS LONG AS TWENTY TO FORTY YEARS BEFORE THE EFFECTS OF EVEN A SHORT EXPOSURE TO ASBESTOS BEGIN TO SHOW.

RESEARCH ON THE ISSUE OF ASBESTOS CONTAMINATION HAS BEEN THE SUBJECT OF CONSIDERABLE DEBATE, ESPECIALLY DURING THE PAST FIVE YEARS. SCIENTISTS ARE TRYING TO DETERMINE THE LEVELS AT WHICH THERE IS A POTENTIAL HEALTH HAZARD, THE EFFECT OF DIFFERENT TYPES OF ASBESTOS ON PEOPLE EXPOSED TO THEM, AND THE LENGTH OF TIME THAT EXPOSURE MUST TAKE PLACE BEFORE THERE IS A HEALTH RISK. FOR THOSE OF US WHO ARE RESPONSIBLE FOR OUR SCHOOL CHILDREN AND THE STAFFS WHO SERVICE THEM, OUR CHARGE IS A STRAIGHT-FORWARD ONE -- WE MUST ADDRESS THE QUESTION OF HOW TO ELIMINATE THE POTENTIAL DANGER TO OUR STUDENTS.

I HAVE COME HERE TODAY TO HELP CRYSTALIZE IN YOUR MINDS THE URGENCY OF THE ASBESTOS SITUATION -- ESPECIALLY IN NEW JERSEY, WHERE OFFICIALS HAVE NOT REACTED QUICKLY TO THE ASBESTOS SITUATION BECAUSE IT SEEMS SO INNOCUOUS. IF ASBESTOS GAVE OFF AN OBNOXIOUS ODOR AND IF PEOPLE WERE BECOMING ILL INSTANTLY, THERE WOULD BE NO QUESTION -- ACTION WOULD BE WOULD BE IMMEDIATE. HOWEVER, BECAUSE THE DISEASES OF ASBESTOSIS, MESOTHELIOMA, AND LUNG CANCER DO NOT SURFACE FOR TWENTY TO FORTY YEARS, PEOPLE ARE NOT COGNIZANT OF THE TRUE URGENCY OF THE SITUATION. ASBESTOS WORKERS COME DOWN WITH THESE DISEASES LATE IN LIFE. BUT, THE CHILDREN NOW BEING EXPOSED TO THESE FIBERS WILL BE IN THEIR PRIME YEARS -- THEIR TWENTIES AND THIRTIES, WHEN BREATHING WILL BECOME DIFFICULT AND, FOR SOME THAT MAY BE THE END OF THEIR LIVES.

I WOULD NOW LIKE TO SHARE WITH YOU OUR SPECIAL CONCERNS ABOUT THE REMOVAL OF ASBESTOS FROM ALL SCHOOLS.

(1) THE EXPOSURE OF CHILDREN AND ADOLESCENTS TO ASBESTOS IN SCHOOL BUILDINGS OCCURS EARLY IN THEIR LIFE SPAN. THEIR REMAINING LIFE EXPECTENCY PROVIDES A LONG DEVELOPMENT PERIOD FOR ASBESTOS-RELATED DISEASES.

(2) IN THE PAST, EXPOSURE TO ASBESTOS HAD BEEN ONLY ASSOCIATED WITH A CHRONIC AND DEBILITATING LUNG DISEASE CALLED ASBESTOSIS. MORE RECENTLY, EXPOSURE TO ASBESTOS HAS BEEN ASSOCIATED WITH LUNG CANCER AND THE RARE TYPE OF CANCER OF THE CHEST AND ABDOMINAL LINING CALLED MESOTHELIOMA. THERE HAVE NOW BEEN REPORTED CASES OF MESOTHELIOMA OF THE ESOPHAGUS, STOMACH, COLON AND OTHER ORGANS. ASBESTOS ALSO ACTS AS A POTENT CANCER-CAUSING AGENT IN COMBINATION WITH CIGARETTE SMOKING.

(3) THE SCHOOL POPULATION IS VERY ACTIVE. CERTAIN ASBESTOS-CONTAINING MATERIALS CAN BE DAMAGED DURING SCHOOL ACTIVITIES AND AS A RESULT OF THE CAPRICIOUS BEHAVIOR OF CHILDREN. WHEN THE MATERIAL IS DAMAGED,

ASBESTOS FIBERS ARE RELEASED AND EXPOSURE CAN OCCUR. MANY CASES OF BADLY DAMAGED ASBESTOS-CONTAINING MATERIALS HAVE BEEN FOUND IN SCHOOLS, SUCH AS IS THE CASE OF OUR SCHOOLS IN CAMDEN.

(4) THERE IS NO WAY TO DETECT ASBESTOS-RELATED ILLNESSES IN CHILDREN DUE TO THE LONG INDUCTION PERIOD BEFORE THE DISEASE APPEARS.

(5) WITH ASBESTOSIS, THE VICTIM NOTICES AN INSIDIOUS ONSET OF EXERTIONAL SHORTNESS OF BREATH AND A REDUCED EXERCISE TOLERANCE. SYMPTOMS OF AIRWAY DISEASE SUCH AS COUGHING AND WHEEZING ARE NOT UNUSUAL. AS IT PROGRESSES, SYMPTOMS BECOME MORE SEVERE AND ULTIMATELY, RESPIRATORY FAILURE WITH MARKED IMPAIRMENT IN OXYGENATION OCCURS. THERE IS NO SPECIFIC THERAPY OR TREATMENT FOR ASBESTOSIS.

(6) MESOTHELIOMA TUMORS ASSOCIATED WITH ASBESTOS EXPOSURE ARE INVARIABLY FATAL. IT IS MORE DIFFICULT TO DIAGNOSE AND MAY BE CONFIRMED ONLY AT AUTOPSY.

(7) A LARGE NUMBER OF STUDENTS CAN BE EXPOSED AT ONE TIME TO ASBESTOS THAT IS RELEASED FROM ASBESTOS-CONTAINING MATERIAL PRESENT IN A SCHOOL BUILDING. THE DURATION OF EXPOSURE IS OF CONCERN SINCE SCHOOL CHILDREN ATTEND SCHOOL DAILY FOR MOST OF THE YEAR.

ASBESTOS-RELATED CANCERS WHICH SHOW UP SO MUCH LATER IN LIFE CAN BE PRECIPITATED BY EXPOSURE TO VERY LOW CONCENTRATION LEVELS FOR A PERIOD AS SHORT AS ONE MONTH OR TWO. THIS SHORT EXPOSURE TIME IS ESPECIALLY CRITICAL WHEN THE EXPOSURE IS TO "FRIABLE ASBESTOS" WHICH IS BASICALLY THE LOSELY BOUND MATERIALS THAT CAN RELEASE ASBESTOS FIBERS AFTER ONLY A MINOR DISTURBANCE.

FOR EXAMPLE, YOU MAY RECALL SEEING COVERINGS AROUND HOT WATER PIPES THAT LEAD INTO CLASSROOMS. IF THE STUDENT WALKS INTO IT, KICKS IT, OR BUMPS A DESK OR CHAIR INTO IT, THAT MILD CONTACT COULD BE SUFFICIENT TO RELEASE FRIABLE MATERIALS INTO THE ATMOSPHERE WHICH SUBSEQUENTLY CAN BE INGESTED AND CONTAINED IN THE LUNGS. EVEN FLOOR VIBRATIONS IN MULTI-STORY BUILDINGS COULD RELEASE FRIABLE ASBESTOS FIBERS INTO THE ATMOSPHERE OF CLASSROOMS ON LOWER LEVELS.

FRIABLE ASBESTOS MATERIALS ARE ESPECIALLY COMMON IN OVERHEAD SURFACES, CEILINGS AND ON THE WALLS AND PIPES -- SUCH AS THE HOT WATER PIPES WE SPOKE OF, WHICH ARE AT GROUND LEVEL, AND THEREBY CONTRIBUTE TO AIR CONTAMINATION BOTH FROM THE CEILING AND FROM THE FLOOR.

LET'S EXAMINE SOME OF THE UNIQUE CIRCUMSTANCES SURROUNDING EXPOSURE TO ASBESTOS THAT OCCUR IN SCHOOL BUILDINGS AND, SPECIFICALLY, TO THE YOUNG PEOPLE WHO OCCUPY THOSE BUILDINGS.

WHY IS THIS ASBESTOS PROBLEM CRITICAL WITH CHILDREN?

1. IN SCHOOL BUILDINGS, THE MAJOR OCCUPANTS ARE CHILDREN. SINCE THEIR LIFE EXPECTANCY IS OVER 60 YEARS, THERE IS MUCH TIME FOR DISEASE TO DEVELOP.

2. CHILDREN ARE MORE SUSCEPTIBLE TO CANCER BECAUSE OF RAPID AND ABUNDANT CELL GROWTH.

3. SINCE CHILDREN SPEND A GREAT AMOUNT OF TIME IN SCHOOL, THEY COULD BE EXPOSED TO HIGH LEVELS IN CONTAMINATED AREAS.

4. THE SCHOOL POPULATION IS INTENSELY ACTIVE. STUDENTS CAN CAUSE DESTRUCTION AND FLAKING OF FIBERS, THUS CONTAMINATION, WITH THEIR NORMAL ACTIVITIES.

5. CHILDREN WHO SMOKE AND WHO ARE EXPOSED TO ASBESTOS HAVE NINTY-TWO TIMES THE CHANCE OF GETTING CANCER AS A PERSON WHO DOES NOT SMOKE AND IS NOT EXPOSED.

6. CHILDREN HAVE A HIGHER RATE OF AIR EXCHANGE -- THEY BREATHE UP TO THREE TIMES THE AMOUNT OF AIR AS AN ADULT, THUS BREATHE IN MORE FIBERS

7. BREATHING INCREASES WITH GREATER ACTIVITY, THUS CHILDREN INHALE GREAT AMOUNTS WHILE PLAYING.

8. WHEN EXCITED OR ACTIVE CHILDREN TEND TO MOUTH BREATHE, THUS LOSING NATURAL NASAL FILTERING.

9. CHILDREN ARE SHORTER -- GET SIGNIFICANTLY HIGHER EXPOSURE CLOSER TO THE GROUND.

WITH RESPECT TO SCHOOL BUILDINGS, THE FOLLOWING PROBLEMS EXIST:

1. THE MOST SERIOUSLY DAMAGED CEILINGS OCCUR IN SCHOOLS. VANDALISM IN SCHOOLS CAUSES VAST DESTRUCTION ON CEILINGS AND ULTIMATELY CONTAMINATION.

2. BECAUSE DAMAGE IS LIKELY IN SCHOOLS, CONCENTRATIONS OF ASBESTOS ARE LIKELY TO BE SIGNIFICANTLY HIGHER THAN OUTSIDE AIR.

3. AIR LEVELS ARE SIGNIFICANTLY HIGHEST AFTER CONTACT -- SWEEPING, DUSTING, ETC.

HAVING TALKED ABOUT THE PROBLEM AND THE SPECIAL VULNERABILITY OF CHILDREN BY VIRTUE OF THEIR CONSTANT AND EXTENDED EXPOSURE IN SCHOOL BUILDINGS, I WOULD LIKE TO REVIEW FROM AN HISTORICAL PERSPECTIVE WHAT HAS BEEN DONE TO DATE. IN 1972, DR. IRVING SALOKOFF, AND OTHERS AT THE MOUNT SINAI SCHOOL OF MEDICINE AND ENVIRONMENTAL SCIENCE LABORATORY PUBLISHED AN ARTICLE ENTITLED "ASBESTOS AIR POLLUTION" WHICH WAS PUBLISHED IN THE ARCHIVES OF ENVIRONMENTAL HEALTH. THAT ARTICLE CONCLUDED THAT BRIEF, HIGH-LEVEL EXPOSURE AS WELL AS LONG-TERM LOW-LEVEL EXPOSURE TO ASBESTOS LEADS TO AN INCREASE IN THE RISK OF CANCER IN HUMANS. IT IS SUSPECTED THAT YOUNG CHILDREN MAY BE MORE SUSCEPTABLE AND MORE SENSITIVE THAN ADULTS TO IRRITANTS SUCH AS ASBESTOS FIBERS IN THE ATMOSPHERE. THE STUDY ALSO FOUND A HIGH CORRELATION BETWEEN ASBESTOS-GENERATED LUNG DISEASES AND CIGARETTE SMOKING. IN 1973 THE EPA BANNED THE USE OF SPRAYED ASBESTOS. AROUND THAT TIME, THERE WAS AN ARTICLE BASED ON A STUDY IN

CONNECTICUT WHICH SHOWED A LINK BETWEEN ASBESTOS EXPOSURE AND THE DEVELOPMENT OF MESOTHELIOMA IN SOME THIRTEEN CHILDREN. ALTHOUGH EVIDENCE WAS NOT ENOUGH TO SHOW A POSITIVE LINK, IT INDICATED THE NEED TO DO SOME BETTER ENVIRONMENTAL HISTORIES. EVEN TODAY THERE ARE NO STANDARDS FOR EXPOSURE TO ASBESTOS THAT ARE EXACTLY APPLICABLE TO ITS PRESENCE IN THE AIR OF PUBLIC BUILDINGS SUCH AS SCHOOLS.

IN 1975, THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION PROPOSED A NEW STANDARD FOR OCCUPATIONAL EXPOSURE TO ASBESTOS. THESE REGULATIONS SPECIFYING EITHER PERMISSIBLE OR MAXIMUM EXPOSURES WERE NEVER ACTUALLY ADOPTED AND CAME UNDER SERIOUS DISPUTE. IN 1976, THE NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH PROPOSED TO OSHA A FURTHER REDUCTION IN ITS PROPOSED MAXIMUM EXPOSURE CEILINGS. NEITHER OF THESE STANDARDS WERE, HOWEVER, ADOPTED. THERE ARE, HOWEVER, SOME REGULATIONS WHICH MAY BE USED AS A MEASURING STICK. IN 1977, THE NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION ISSUED SOME STRINGENT REGULATIONS WHICH PARALLELED THE GENERAL ONES OF THE UNITED STATES EPA PROHIBITING THE SPRAYING OF MATERIALS CONTAINING MORE THAN 0.25 PERCENT BY WEIGHT OF ASBESTOS ONTO ANY BUILDINGS OR STRUCTURES, INTERNALLY OR EXTERNALLY. DURING THAT SAME YEAR, THE NEW JERSEY DEPARTMENT OF EDUCATION BANNED THE SPRAYING ON OF SURFACE COATINGS CONTAINING ASBESTOS IN THE SCHOOL BUILDINGS.

ONE OF THE MAJOR PROBLEMS WITH ALL OF THE STANDARDS AND REGULATIONS THAT WERE PROPOSED UP TO THAT POINT IS THAT THEY RELATED ONLY TO THE LEVELS OF ASBESTOS THAT WERE SUPPOSED TO BE LESS THAN NECESSARY TO PRODUCE ASBESTOSIS. HOWEVER, THERE IS NO HARD DATA AVAILABLE TO INDICATE WHAT A SAFE LEVEL OF ASBESTOS IS IN RELATION TO THE DANGER OF CANCER. FURTHER, THE LONG LATENCY PERIOD IS SUCH THAT IT MAKES IT VERY DIFFICULT, TIME CONSUMING AND SUBJECT TO SUBSTANTIAL INACCURACIES TO UTILIZE RECORDS AND STANDARDS OF THE DISTANT PAST.

IN 1977, THE IDENTIFIED POTENTIAL HAZARDS OF ASBESTOS CAME TO A HEAD WHEN A PARENT WHO WORKED AS A SUPERIVSOR IN THE STATE DEPARTMENT OF ENVIRONMENTAL PROTECTION AND WHO WAS OBVIOUSLY WELL-VERSED WITH THE STUDIES THAT HAD BEEN DONE ON ASBESTOS HAD A SAMPLE TESTED. THE PARENT CAME TO A SCHOOL BOARD MEETING OF THE HOWELL TOWNSHIP SCHOOLS AND DISCUSSED THE DANGER TO THE STUDENTS AND STAFF. THIS SET OFF A FUROR IN THE LOCAL SCHOOLS AS THE PARENTS LIVING IN A STATE THAT ALREADY HAS ONE OF THE HIGHEST CANCER RATES IN THE NATION BEGAN TO REACT TO THE POTENTIAL DANGER TO THEIR CHILDREN. THE RESULT WAS THAT BY THE MIDDLE OF THE YEAR, THE SCHOOLS WERE CLOSED FOR A PERIOD OF SOME FOUR WEEKS AND AFTER EXTENSIVE DISCUSSION AND DEBATE AND MUCH EMOTION THE ASBESTOS WAS REMOVED FROM THE SCHOOLS WITH THE FINAL COST OF $180,000.

THE CRISIS, THE REACTION OF THE COMMUNITY, AND THE SOLUTION TO THE PROBLEM IS ONE THAT RECEIVED NOT ONLY LOCAL, BUT STATEWIDE AND NATIONAL ATTENTION. THE RESULT WAS THAT MORE ATTENTION WAS FOCUSED ON THE CONCERNS OF ASBESTOS CONTAMINATION, ITS HEALTH HAZARDS, AND THE NEED TO (1) ESTABLISH STANDARDS FOR ITS DANGER AND (2) IDENTIFY SPECIFIC ACCEPTABLE PROCEDURES FOR THE ELIMINATION OF THAT DANGER.

IN MARCH 1978, THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY RELEASED ITS FIRST GUIDANCE DOCUMENT ENTITLED "SPRAYED ASBESTOS-CONTAINING MATERIALS IN SCHOOL BUILDINGS." IN THAT DOCUMENT REFERENCES WERE MADE TO VARIOUS ACTIONS THAT MAY BE TAKEN IN THOSE AREAS AFFECTED WITH ASBESTOS. THE DOCUMENT ALSO DISCUSSED TEMPORARY VERSUS LONG-TERM CONTROL MEASURES AND THE STATE OF THE ART REGARDING SUCH THINGS AS SEALANTS FOR ENCAPSULATING THE ASBESTOS FIBERS AND THE KINDS OF PROCEDURES THAT HAD TO BE ADHERED TO IF REMOVAL AND DISPOSAL WAS TO BE THE OPTION. DURING THAT PERIOD, THERE WERE THREE WAYS TO DEAL WITH THE ASBESTOS: (1) ENCAPSULATION WHICH IS THE SPRAYING OF THE ASBESTOS WITH MATERIAL THAT WOULD PREVENT THE FIBERS FROM BEING AIRBORNE, (2) ENCLOSURE, WHICH IS NOTHING MORE THAN BUILDING MATERIALS SUCH AS A FALSE CEILING AROUND THE ASBESTOS, OR (3) TOTAL REMOVAL.

INDEPENDENT RESEARCH DONE BY DR. ROBERT [illegible]AWYER OF YALE UNIVERSITY, WHO WAS THE PRINCIPLE CONSULTANT IN THE PREPARATION OF THE EPA GUIDANCE DOCUMENT, HAD IDENTIFIED A MEANS BY WHICH ASBESTOS FIBERS MAY BE RELEASED INTO THE ENVIRONMENT. IN SO DOING, DR. SAWYER HAS SHOWN THAT CHILDREN MAY BE EXPOSED TO AN ABNORMALLY HIGH NUMBER OF ASBESTOS FIBERS IN SCHOOLS WHERE SPRAYED ON ASBESTOS SURFACE MATERIALS ARE DETERIORATING DUE TO THE GRADUAL BREAKDOWN OF THE BONDING AGENT USED IN SUCH MATERIALS. HE HAS SHOWN THAT SUCH FIBERS REMAIN AIRBORNE FOR LONG PERIODS OF TIME AND MAY BE REINTRODUCED INTO THE ENVIRONMENT BY MEANS OF THE USUAL DRY CLEANING, DUSTING, AND SWEEPING PROCEDURES THAT ARE USED IN SCHOOLS. THEN TOO, MAINTENANCE AND REPAIR PERSONNEL MAY BE EXPOSED TO HIGH LEVELS OF ASBESTOS FIBER CONCENTRATIONS FOR SHORT PERIODS OF TIME AS THEY CUT, DRILL INTO SAND, OR EVEN PAINT OVER FRIABLE ASBESTOS MATERIALS.

THE HAZARDS WITH ENCAPSULATION AND ENCLOSURE BECOME RATHER APPARENT UPON CLOSE EXAMINATION BECAUSE SOONER OR LATER WHEN THE SPRAYED MATERIAL IS CRACKED OR DISINTERGRATES, OR WHEN THE ENCLOSURE IS REMOVED OR TAPPED, THE ASBESTOS THAT IS CONTAINED WITHIN REMAINS AND PRESENTS AN ULTIMATE THREAT. SUBSEQUENT CONCLUSIONS REACHED BY EVERYONE IS THAT THE ONLY SOLUTION IS THE COMPLETE REMOVAL OF THE PROBLEM AND ITS POTENTIAL EXPOSURE TO HUMANS.

THE COMMISSIONER OF EDUCATION IN NEW JERSEY IN 1977, BEFORE THE EPA DOCUMENT WAS RELEASED, SENT A DIRECTIVE TO EVERY COUNTY SUPERINTENDENT IN THE STATE REQUESTING A SURVEY OF ALL THE SCHOOL DISTRICTS IN EACH OF THEIR COUNTIES ON THE POSSIBLE PRESENCE OF ASBESTOS IN SCHOOL BUILDINGS; DISTRICTS WERE TO REPORT ON THE CONDITIONS OF SUCH MATERIALS AND SUGGEST REMEDIAL ACTION. AS A RESULT OF THE SURVEY THAT WAS DONE AT THAT TIME, SOME 265 SCHOOLS IN 142 DISTRICTS REPORTED THE PRESENCE OF ASBESTOS MATERIAL. IN THE SUMMER OF 1977, NIOSH-FUNDED INVESTIGATORS FROM THE MT. SINAI SCHOOL OF MEDICINE VISITED 21 OF THE SELECTED DISTRICTS WITH 48 SCHOOLS TO DEFINITIVELY CHECK FOR THE PRESENCE OF ASBESTOS. ONLY TWO OF THE SIXTY-FOUR SAMPLES IN TWO SCHOOLS FAILED TO REVEAL THE PRESENCE OF ASBESTOS.

IN THE TESTING, ONE OF THE THINGS THAT WAS APPARENT WAS THAT UNUSUALLY HIGH CONCENTRATIONS EXISTED IN THOSE SITUATIONS WHERE THE ASBESTOS WAS IN A LOOSE FIBEROUS MAT AND INVISIBLE DAMAGE HAD OCCURRED TO THE SURFACE, SUCH AS MIGHT TYPICALLY OCCUR IN SCHOOL BUILDINGS WITH LOTS OF STUDENT CONTACT.

SUBSEQUENTLY, IN 1979, THE UNITED STATES ENVIROMENTAL PROTECTION AGENCY ANNOUNCED THAT IT WAS GOING TO REQUIRE OFFICIALS TO INSPECT SCHOOLS AND REMOVE DANGEROUS LEVELS OF ASBESTOS CONTAMINATION. THE PLAN WAS DELAYED AND EVENTUALLY DROPPED BY THE CURRENT ADMINISTRATION. HOWEVER, THE EPA DID ANNOUNCE A NEW REGULATION IN MAY OF 1982 REQUIRING EACH STATE TO INSPECT ALL PUBLIC SCHOOL BUILDINGS BY JUNE, 1983. THAT INSPECTION HAS JUST BEEN COMPLETED AND THE COMPILATION OF THAT DATA WAS UNFORTUNATELY NOT AVAILABLE TO US IN TIME TO REPORT TO YOU AT TODAY'S HEARING.

IN ADDITION TO REGULATIONS, CONGRESS RECOGNIZED THE NEED FOR LEGISLATION AND IN 1980, PASSED THE "ASBESTOS SCHOOL HAZARD DETECTION AND CONTROL ACT", CO-SPONSORED BY NEW JERSEY SENATOR BILL BRADLEY, WHICH WAS DESIGNED TO DEVELOP A PROGRAM OF ASBESTOS CONTROL AND TO PROVIDE FUNDS FOR DETECTION AND ABATEMENT. THAT ACT, WHICH WAS SIGNED BY FORMER PRESIDENT CARTER IN JUNE 1980 AS PUBLIC LAW 96-270, PROVIDED GRANTS AND LOANS TO DETECT AND REMOVE ASBESTOS. THE BILL AUTHORIZED $172.5 MILLION; HOWEVER, IT REQUIRED APPROPRIATIONS BY CONGRESS WHICH, TO MY KNOWLEDGE, NEVER DID OCCUR. BECAUSE THERE WAS NO FUNDING APPROPRIATED, THE EDUCATION DEPARTMENT RELEGATED THE INFORMATIONAL PROGRAM TO A LOW PRIORITY, ACCORDING TO THE GENERAL ACCOUNTING OFFICE. AS A RESULT, FEDERAL EFFORTS TO HELP SOLVE THE ASBESTOS PROBLEM IN SCHOOLS HAVE BEEN OF LITTLE HELP TO STATES SEARCHING FOR WAYS TO IDENTIFY AND DEAL WITH THE PROBLEM. THE 1980 LAW ALSO PROVIDED FOR AN ASBESTOS HAZARD SCHOOL SAFETY TASK FORCE WHICH WAS APPOINTED BY THE SECRETARY OF EDUCATION, BUT HAS NOT MET SINCE 1980.

THE EPA REGULATION IN 1982 BROUGHT TO PUBLIC LIGHT RENEWED INTEREST IN THE ASBESTOS PROBLEM. AS OF THE END OF THIS PAST JUNE 1983, DISTRICTS WERE REQUIRED TO POST A NOTICE IN ALL SCHOOL BUILDINGS WARNING THAT THEY CONTAIN ASBESTOS WHERE IT HAS BEEN IDENTIFIED. IN ADDITION, ALL PEOPLE EMPLOYED WERE TO RECEIVE WRITTEN NOTICE OF THE PRESENCE AND LOCATION OF ASBESTOS IN THE SCHOOL BUILDING. THEREFORE, AS YOU MIGHT WELL IMAGINE, WE HAVE CONSIDERABLE CONCERN ABOUT THE HYSTERIA AND FEAR SURROUNDING THIS SUBJECT THAT WILL OCCUR AND THAT WILL BE ALLOWED TO PREVAIL. IT WILL PREVAIL PRIMARILY BECAUSE OF THE LACK OF PRECISE GUIDELINES REGARDING WHAT THE ULTIMATE IMPACT ON THE HEALTH OF OUR STUDENTS AND STAFF MIGHT BE AND THE LACK OF SUFFICIENT MONEY TO TAKE THE ONE AND ONLY VIABLE ALTERNATIVE WHICH SEEMS TO BE AGREED ON; THAT IS, REMOVAL. IT IS CLEAR THAT WITH THE POSTING OF THESE NOTICES, ANXIOUS PARENTS, EMPLOYEES, AND OTHER PERSONS WILL BE ASKING US TO DO SOMETHING ABOUT THE ASBESTOS PROBLEM.

NONE OF THE PROGRAMS THAT HAVE BEEN ESTABLISHED TO DATE REALLY WORK. THE ASBESTOS TASK FORCE THAT WAS ESTABLISHED UNDER THE DEPARTMENT OF EDUCATION NEVER FINISHED ITS JOB OF DETERMINING WHEN THE SUBSTANCE IS

HAZARDOUS IN SCHOOLS. FURTHERMORE, THE REGULATIONS WHICH SPELL OUT PROCEDURES FOR DETECTION AND CONTROL WERE PUBLISHED IN JANUARY 1981. BUT THOSE RULES, LIKE THOSE OF THE EPA, DID NOT SPECIFY WHEN SCHOOLS SHOULD REMOVE ASBESTOS.

THE EPA TECHNICAL ASSISTANCE PROGRAM WAS SOMEWHAT MORE EFFECTIVE, ALTHOUGH IT WAS VOLUNTARY. ONCE AGAIN, ACCORDING TO THE GENERAL ACCOUNTING OFFICE, SCHOOLS WERE NOT GIVEN RELIABLE CRITERIA FOR DETERMINING WHEN TO REMOVE ASBESTOS. THE EPA IS IN THE PROCESS OF VERIFYING A NEW METHOD TO DETERMINE ASBESTOS HAZARDS AND IS EXPECTED TO COME UP WITH SOME MORE PRECISE AND DEFINITIVE GUIDELINES. INTERESTINGLY ENOUGH, IT WAS A CONTINGENT OF OFFICIALS REPRESENTING THE STATE OF NEW JERSEY WHO IN 1979 IN HEARINGS BEFORE CONGRESSIONAL COMMITTEES WHO REQUESTED THE EPA REGULATION TO CONTROL ASBESTOS CONTAMINATION IN BUILDINGS. THE RULE, HOWEVER, WHICH WAS ISSUED IN MAY 1982 WAS VERY SIMILAR TO THE RULE THAT WAS PROPOSED IN 1980 AND WHICH IN BOTH CASES DOES NOT PROVIDE ANY ADDITIONAL GUIDANCE ON WHEN ASBESTOS IS HAZARDOUS AND NEEDS ABATEMENT.

IN THE CITY OF CAMDEN, WHERE I SERVE AS SCHOOL BOARD PRESIDENT, WE HAD OUR FIRST ACTIVE ENCOUNTER WITH ASBESTOS CONTAMINATION, OR AT LEAST THE RECOGNITION THEREOF, IN NOVEMBER, 1981. AT THAT TIME WE HAD A LEAK IN THE ROOF OF CAMDEN CITY'S HIGH SCHOOL WHICH PUFFED UP AND CREATED A SERIOUS PROBLEM IN TERMS OF RELEASING FRIABLE ASBESTOS MATERIALS IN THE AIR. WE SELECTED THE APPROACH OF COMPLETE REMOVAL AT CONSIDERABLE COST. FROM THAT TIME UNTIL THE PRESENT, IN OUR EFFORTS TO DETECT AND IDENTIFY ASBESTOS AND THE LEVELS THEREOF, WE HAVE HAD TO APPROPRIATE IN OUR 1983-84 BUDGET ALONE NEARLY $460,000 FOR THE REMOVAL OF ASBESTOS CONTAMINATION. OUR MAJOR PROBLEM IN PROCEEDING WITH THIS WORK WAS THE TIME WE LOST IN GETTING AN ADEQUATE CONSULTANT AND THE ABSENCE OF DEFINITIVE GUIDELINES FROM ANY OF THE STATE AGENCIES WITH RESPECT TO SPECIFICATIONS TO ADVERTISE FOR CONSULTANTS, OR WITH RESPECT TO SPECIFICATIONS ON THE PRECISE NATURE OF THE PROBLEM AND THE SPECIFIC SOLUTIONS THAT MIGHT BE REQUIRED.

WE ARE A CITY WHICH HAS BEEN FIGHTING FOR SURVIVAL, WHICH IS SUFFERING THE FLIGHT TO THE SUBURBS, WHICH IS ATTEMPTING TO INSTITUTE ITS REBIRTH, WHICH IS LIVING WITH DECLINING PROPERTY VALUES, INDUSTRIAL RATABLES LEAVING FOR MORE ALLURING SITES, WITH AN EVER-INCREASING POVERTY POPULATION AND WITH ESCALATING COSTS FOR SCHOOL THAT HAVE BECOME BURDENSOME AND ALMOST IMPOSSIBLE FOR MANY OF THE TAXPAYERS

WE ARE A DISTRICT WHICH RECEIVES MORE THAN 80 PERCENT OF OUR TOTAL COST PER PUPIL IN EDUCATION FROM THE STATE BECAUSE OF OUR INABILITY TO RAISE THAT AMOUNT OF MONEY OUT OF OUR OWN PALTRY TAX RESOURCES. CONSIDERING THAT SITUATION, IT IS EXTREMELY DIFFICULT FOR US TO FACE THE PROBLEMS OF TRYING TO ABSORB THE VERY EXPENSIVE COSTS FOR THE REMOVAL OF THE ASBESTOS CONTAMINATION IN THE MANY SCHOOL BUILDINGS WHERE OUR STAFF AND STUDENTS FACE THE POTENTIAL HEALTH HAZARD.

WE ARE DESPERATELY IN NEED OF HELP AND THAT IS ONE OF THE REASONS WHY I AM HERE. THE SUBURBAN COMMUNITY JUST NORTH OF US, THE TOWNSHIP OF CINNAMINSON, I BELIEVE, TESTIFIED BEFORE ONE OF THE CONGRESSIONAL COMMITTEES JUST A FEW YEARS AGO. THEY TOO, ALBEIT WEALTHIER THAN OUR CITY, ARE SUFFERING A SIMILAR KIND OF PROBLEM IN THAT THE POTENTIAL COST FOR THE REMOVAL OF THE ASBESTOS THREAT WHICH EXISTS IN THEIR COMMUNITY IS EXTENSIVE COMPARED TO THEIR TAX BASE. THEY TOO FACE THE ALTERNATIVE OF HAVING TO REDUCE EDUCATIONAL OPPORTUNITIES FOR THEIR YOUTH IN ORDER TO BE ABLE TO PROVIDE FOR THEIR PHYSICAL SAFETY, OR AT LEAST TO REMOVE A THREAT TO THEIR PHYSICAL WELL BEING.

IN THE MEANTIME, ANOTHER EXAMPLE IS THE CITY OF PLAINFIELD IN THE NORTHERN PART OF THE STATE WHERE 15 BUILDINGS HAVE BEEN IDENTIFIED WITH DISTINCT ASBESTOS PROBLEMS, WITH RANGES OF FRIABLE ASBESTOS FROM VERY LOW CONCENTRATIONS TO VERY HIGH ONES COMPARED TO WHAT MIGHT BE FOUND IN MANUFACTURING CONCERNS THAT ACTUALLY PRODUCE SUCH MATERIAL. AMONG THE ALTERNATIVES THAT PLAINFIELD FACES FOR THIS YEAR ARE COSTS OF BETWEEN $480,000 AND $965,000 FOR REMOVAL OF THE EXISTING CONTAMINATION THAT HAS BEEN DETECTED IN THAT SCHOOL SYSTEM TO DATE.

ALTHOUGH IT IT IS A DIFFICULT ONE, OUR SITUATION IN CAMDEN IS BY NO MEANS UNIQUE. THROUGHOUT THE STATE OF NEW JERSEY, ASBESTOS MATERIALS WERE INCORPORATED INTO SCHOOL BUILDINGS ON THE ADVICE OF REPUTABLE ARCHITECTUAL AND ENGINEERING FIRMS RIGHT UP INTO THE EARLY 1970s. WHEN THE DANGERS OF ASBESTOS SUBSEQUENTLY BECAME WIDELY KNOWN, SCHOOL DISTRICTS WERE CONFRONTED WITH THE REALITY OF SCHOOL CHILDREN BEING ENDANGERED BY THE VERY FACILITIES BUILT TO NUTURE AND CULTIVATE THEM. PARENTS AND COMMUNITIES WERE OUTRAGED AND CONCERNED, BUT SOLUTIONS TO THE PROBLEM INVARIBLY DEPENDED UPON FINANCIAL CONSIDERATIONS. THE ABILITY TO COPE WITH THE CONSIDERABLE EXPENSE OF ASBESTOS REMOVAL VARIES WIDELY AMONG NEW JERSEY'S SCHOOL DISTRICTS AND AT BEST HAS COMPROMISED EQUALITY OF EDUCATIONAL OPPORTUNITY. MANY DISTRICTS, FACED WITH THE INESCAPABLE LIMITATIONS IN SPENDING IMPOSED BY BUDGET CAPS AND DWINDLING RESOURCES, HAVE BEEN UNABLE TO EVEN BEGIN REMOVING THE HAZARDOUS MATERIAL FROM THEIR SCHOOLS. OTHERS HAVE BEEN FORCED TO CUT BACK IN VITAL AREAS SUCH AS CURRICULAR PROGRAMS TO COMPENSATE FOR FUNDS UNEXPECTEDLY NEEDED FOR ASBESTOS REMOVAL. EITHER WAY, OUR CHILDREN HAVE BEEN THE LOSERS.

IN 1977, 250 SCHOOLS OF THE 2,400 SCHOOLS IN THE STATE IDENTIFIED PROBLEMS WITH FRIABLE ASBESTOS. AS OF MARCH, 1983, 165 OF THOSE HAVE TAKEN CORRECTIVE ACTION AND HAVE EXPENDED $20.3 MILLION FOR THE REMOVAL OF THE ASBESTOS AND RELATED WORK. AS OF JUNE, 1983, 283 OF THE 2,400 SCHOOL BUILDINGS IN OUR STATE -- OVER 10 PERCENT -- HAD ALREADY IDENTIFIED AND RECEIVED STATE APPROVAL FOR THE REMOVAL OF ASBESTOS HAZARDS AT A TOTAL OF $36.6 MILLION. OUR DEPARTMENT OF EDUCATION ESTIMATES THAT AT LEAST 200 CASES WILL ARISE IN THE NEAR FUTURE, AS A RESULT OF THE RECENTLY COMPLETED LOCAL INSPECTION REQUIRED BY THE FEDERAL EPA. EVEN BASED ON CONSERVATIVE ESTIMATES -- AN AVERAGE OF 10,000 SQUARE FEET PER SCHOOL REMOVED AT $10 TO $17 A FOOT -- AN ADDITIONAL EXPENDITURE OF $20 TO $34 MILLION WOULD RESULT. NEW JERSEY'S HARD-PRESSED SCHOOL DISTRICTS SIMPLY CANNOT AFFORD SUCH A COST, PARTICULARLY AT A TIME OF DIMINISHING FEDERAL AND STATE SUPPORT IN OTHER AREAS.

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, I DO NOT BELIEVE THAT WE CAN ANY LONGER SUGGEST THAT THERE IS ANY DOUBT THAT ASBESTOS IS A FACTOR IN CAUSING THE DEBILITATING LUNG DISEASE ASBESTOSIS, THAT IT IS A POTENT CANCER-CAUSING AGENT, AND THAT ITS EXISTENCE IS EXACERBATED BY CIGARETTE SMOKING. IT IS CLEAR THAT LOW-LEVEL EXPOSURE AND EVEN SHORT PERIODS OF EXPOSURE PRESENT A POTENTIALLY SIGNIFICANT HEALTH HAZARD. IT IS ALSO VERY CLEAR THAT THERE IS A LARGE NUMBER OF PUBLIC BUILDINGS, AND MOST PARTICULARLY FROM MY VANTAGE POINT, PUBLIC SCHOOL BUILDINGS IN WHICH OUR YOUNG PEOPLE, THE FUTURE OF OUR COUNTRY, AND THE STAFF AND EMPLOYEES WHO SERVE THEM ARE ALL EXPOSED TO THIS POTENTIAL HAZARD IN SCHOOLS THAT CONTAIN THIS MATERIAL.

I THINK YOU WOULD ALL ALSO AGREE THAT THE SCIENTIFIC COMMUNITY, AS WELL AS THE ENVIRONMENTAL PROTECTION AGENCY HAVE COME TO THE BELIEF THAT EXPOSURE TO ASBESTOS AT ANY LEVEL INVOLVES SOME HEALTH RISK. IT IS MY BELIEF THAT IF THERE IS SOME RISK, THEN THAT RISK MUST BE REMOVED. WHILE THE COST IS VERY EXPENSIVE AND DIFFICULT FOR MANY DISTRICTS TO AFFORD, IT IS NOT BEYOND THE MEANS AND THE CAPABILITY OF THE RESOURCES OF THE FEDERAL GOVERNMENT. THERE ARE DISTRICTS WITHIN THE STATE OF NEW JERSEY, FOR EXAMPLE, WHERE IN SPITE OF POTENTIAL HAZARD, VOTERS HAVE TURNED DOWN BOND REFERENDUMS TO RAISE THE MONIES FOR THE COST OF REMOVAL. THE REASONS FOR DEFEAT HAVE NOT BEEN BECAUSE OF A LACK OF SYMPATHY FOR THE PROBLEM; THEY HAVE BEEN BECAUSE IN SOME CASES, THOSE COSTS HAVE BEEN PROHIBITED IN COMPARISON TO THE ABILITY OF THOSE INDIVIDUALS TO PAY.

AT TIMES LIKE THESE WHEN LOCAL DISTRICTS AND THE STATE ARE NOT SUFFICIENTLY CAPABLE OF PROVIDING THE ADEQUATE RESOURCES, WE COME TO THE FEDERAL GOVERNMENT FOR WHAT IS NOT ONLY A NEW JERSEY PROBLEM, BUT A NATIONAL PROBLEM OF POTENTIALLY IMMENSE PROPORTIONS. THE GROUP FOR WHOM I ESPECIALLY FEAR ARE OUR YOUNG PEOPLE BECAUSE THEY ARE THE FUTURE OF THIS COUNTRY. WE KNOW THAT THE LONG LATENCY PERIOD BEFORE THE RESULTS OF THIS HEALTH HAZARD BECOMES IDENTIFIABLE IS WHAT HAS LED TO THE "FOOT DRAGGING" AND LETHARGY ASSOCIATED WITH THIS PARTICULAR HEALTH HAZARD. IT IS MY BELIEF, HOWEVER, THAT THE TIME FOR ACTION IS NOW! WE HAD A PROMISE A FEW YEARS AGO WITH THE 1980 LAW THAT SAW NO FUNDING AND NO SUBSEQUENT ACTION. WE CANNOT AFFORD TO BE LULLED INTO COMPLACENCY. THE OMINOUS THREAT THAT WE MIGHT WAKE UP 25 YEARS FROM NOW AND FIND OUR YOUNG LEADERS OF THIS NATION FACING A PREMATURE DEBILITATING DISEASE AND POTENTIALLY DEATH IS UNTHINKABLE.

THE ESTIMATES FOR REMOVAL OF THIS PROBLEM IN THE PUBLIC SCHOOLS OF NEW JERSEY ALONE RANGE AS HIGH AS $50 TO $70 MILLION. I CAN'T SPEAK FOR WHAT THE COST MIGHT BE IN THE OTHER STATES OF THE NATION, BUT IF THAT'S WHAT IT TAKES TO GUARANTEE THAT OUR YOUTH WILL HAVE THE SAME OPPORTUNITIES THAT YOU AND I HAVE HAD, I BELIEVE THAT TO BE A SMALL PRICE TO PAY. ONLY COMPLETE REMOVAL OF ASBESTOS WILL ELIMINATE THE RISK OF ASBESTOSIS OR LUNG CANCER, OR MESOTHELIOMA AND INSURE OUR CHILDREN OF ONE LESS HEALTH HAZARD TO FACE AS THEY APPROACH ADULTHOOD.

MUCH ATTENTION HAS BEEN FOCUSED ON EXCELLENCE IN EDUCATION, AND I DON'T WISH TO RAISE THE SPECTOR OF SCARE TACTICS, BUT FOR THAT EXCELLENCE TO OCCUR, OUR CHILDREN MUST BE ABLE TO LIVE AND LIVE LONG ENOUGH IN ORDER

TO BENEFIT FROM THAT EXCELLENT EDUCATION. THEY MUST ALSO BE FREE FROM THE DEBILITATING ENVIRONMENTAL EXPOSURES TO WHICH WE NOW POTENTIALLY SUBJECT THEM BY VIRTUE OF OUR UNWILLINGNESS, OUR INABILITY, OR DIFFICULTY IN MAKING DECISIONS THAT WE KNOW TO BE RIGHT. THAT RIGHT DECISION IS TO SIMPLY ESTABLISH THE AMOUNT OF FUNDS THAT ARE NECESSARY AND APPROPRIATE THEM TO DO THE ONE AND ONLY THING THAT OUGHT TO BE DONE TO CLEAR UP THE PROBLEM ONCE AND FOR ALL REMOVE THIS HEALTH HAZARD, ASBESTOS, FROM OUR SCHOOLS AND GIVE OUR CHILDREN THE SAME CHANCE THAT WE HAD TO LIVE AND TO GROW AND TO FORGE AHEAD IN THIS GREAT NATION OF OURS!

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, I THANK YOU FOR THE OPPORTUNITY TO COME BEFORE YOU.

BEFORE THE UNITED STATES SENATE
SUBCOMMITTEE ON TOXIC SUBSTANCES AND
ENVIRONMENTAL OVERSIGHT OF THE COMMITTEE
ON ENVIRONMENT AND PUBLIC WORKS

JULY 29, 1983

TESTIMONY OF THOMAS J. DAWSON
WISCONSIN PUBLIC INTERVENOR

INTRODUCTION

I wish to thank you, Mr. Chairman, and honorable members of the Subcommittee on Toxic Substances and Environmental Oversight, for extending to me this opportunity to testify on what I believe to be one of the most important environmental issues of this decade--groundwater contamination by toxic substances.

As Wisconsin Public Intervenor, I am an assistant attorney general in the Wisconsin Department of Justice charged by state law to advocate the protection of public rights in the waters and other natural resources of Wisconsin.

Over the last several years my office has been immersed in the subject of groundwater contamination by various pollutants, including those we classify as toxics. The two top program priorities of the Wisconsin Public Intervenor office are groundwater protection and control of pesticide pollution of the environment. It was pesticide contamination of Wisconsin groundwaters that merged these two top priorities in such a way as to make our office particularly aware of the very real human, environmental and economic impacts that toxics pollution can cause, and of the unique policy dilemmas that it presents.

Over the last several years, the Wisconsin Public Intervenor office has petitioned state agencies for the adoption of administrative rules and regulations for the control of that class of toxic substances that we know as pesticides. I participated in both the 1981 and 1982 rulemaking processes that developed one of the first sets of regulations in the country dealing with aldicarb (Temik) contamination of groundwaters.[1/] I appeared as a "friend of the court" in the unsuccessful attempt of Union Carbide Agricultural Products Company, Inc. to invalidate those rules and regulations. I was a member of two subcommittees of the Wisconsin Legislative Council Special Committee on Groundwater Management which recently developed a legislative proposal for the protection of groundwaters in Wisconsin. I have written, or my office has sponsored the writing of, policy papers, rules and regulations, and legislation for the protection of groundwaters from pesticides, toxic substances, and other pollutants. And I have met with, and spoken on behalf of, numerous victims of groundwater pollution throughout the State of Wisconsin who have suffered immeasurable economic and psychological harm from the contamination of their groundwater.

[1/] These rules, sections Ag 29.18 Wis. Adm. Code (1982) and Ag 29.17 Wis. Adm. Code (1983), are contained in an indexed packet of materials that are offered as an "Addendum" to the required 25 copies of this testimony submitted to the Subcommittee. The packet contains documentatiion of many of the facts, policy papers, administrative findings and rules, proposed legislation, news accounts, position papers, and other materials relating to groundwater pollution in Wisconsin, particularly toxic pesticide pollution, to which this testimony refers.

WISCONSIN'S GROUNDWATER RESOURCE AND ITS CONTAMINATION BY TOXIC SUBSTANCES

Groundwater has recently been described as Wisconsin's "buried treasure." About 94% of Wisconsin's cities and villages get their drinking water from the ground. Virtually every Wisconsin rural resident is dependent on at least one of the 500,000 domestic wells in Wisconsin. Groundwater provides more than 25% of our manufacturers' water needs--approximately 133 million gallons per day. The beef and dairy farms of Wisconsin depend upon approximately 27 billion gallons of groundwater per year. Irrigation equipment withdrew an additional 30 billion gallons of groundwater in Wisconsin in 1981. To say the least, the abundance of quality groundwater is an indispensable component of the economic, as well as environmental and domestic, well-being of Wisconsin citizens.

Although Wisconsin is considered to be a water-rich state, the value of that treasure is being increasingly threatened by toxic and other pollutants. Attached to my testimony is a list of seven pesticides that have been found in Wisconsin groundwaters as a result of a recent pesticide detection program for groundwater (see Exhibit A). Four of those pesticides were found in excess of the United States Environmental Protection Agency (EPA) guidelines. It is also my understanding that EPA recently noted positive findings of eleven pesticides in groundwater samples from thirteen states (see Exhibit B).

Other toxic substances have been found in Wisconsin groundwaters.[2/] Attached to my testimony (as Exhibit C) is a list of 44 chemicals that have been detected in wells adjacent to the so-called "Hagen Dump Site" in Stoughton, Wisconsin, about ten miles from our state's Capitol. This list represents the toxic contaminants from only one abandoned landfill in Wisconsin, but one which has nearly ruined the lives of families that depend on well water adjacent to the site.

"Orphaned" landfills, licensed-but-abandoned landfills, and operating hazardous waste and solid waste landfills are other sources of toxic substances in Wisconsin groundwaters.

In 1982, the Wisconsin Department of Natural Resources' (WDNR) sampling of 208 community water wells found that fifty-one contained detectable amounts of trichloroethylene (TCE) and/or other synthetic chemical compounds. Water from four communities contained amounts sufficient to warrant closing affected wells. In one case, the contamination is expected to last as long as fifty years, and the cost of replacing the well to the community

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[2/] Although this testimony is devoted primarily to toxic contamination of groundwaters, toxic pollution of Wisconsin surface waters poses still additional threats to the health, economic, and environmental well-being of Wisconsin citizens. For example, 2,3,7,8-TCDD (Dioxin) contamination of fish in excess of U.S. Food and Drug Administration standards has resulted in a ban on the harvest of carp on 47 miles of the Wisconsin River and an alert to health officials in New York City, the market for a large portion of the catch. Testing for TCDD contamination of migratory birds in the vicinity of Green Bay is also being conducted at the present time and the results expected soon. Other toxic pollutants have been confirmed in the tissues of animals, river bottom sediments, and waters in Wisconsin.

will be at least $625,000. Water purification processes for the wells may cost the communities in excess of $100,000-$150,000. That is a lot of money for a small rural community in Wisconsin.

The economic costs of groundwater pollution do not measure the human anxiety, justified psychological trauma, potential long-term health threats, and indignity caused to citizens whose ground and drinking water supplies have been contaminated by toxic pollutants. I have seen dairy farmers on the brink of bankruptcy as a result of toxic mining contaminants in their wells. I have seen destitute families with no place to turn for clean drinking water. I have met several families who literally are prisoners in their homes because no one will buy their properties as a result of contamination. And I have seen the legitimate psychological trauma that parents have for their children who have drunk or continue to drink water containing pollutants whose scientific names are too difficult to pronounce, let alone their toxicities to comprehend.

WHAT IS BEING DONE IN WISCONSIN?

Not enough is being done about groundwater pollution in Wisconsin, although significant strides are being made. Congressional leadership and action are needed in conjunction with your review of the Toxic Substances Control Act (TSCA) and other federal laws in order for the following efforts in Wisconsin to have a fair chance of success.

First, WDNR was served, on Tuesday of this week with a petition for the adoption of administrative rules to establish and enforce standards to protect the public from contaminated drinking water. A copy of that petition is included in the separate Addendum of materials which I am submitting to the Committee. It is the latest of a long line of petitions that the Wisconsin Public Intervenor office has sponsored to deal with protection of groundwater supplies. The requested rules would include: 1) the setting of standards for toxic substances; 2) interim enforcement of applicable federal and state health advisories; 3) notice to affected users whose drinking water exceeds applicable contaminant levels; 4) the provision of alternative water supplies; 5) the testing of "at risk" wells in affected areas; 6) investigation of pollution sources; and 7) a requirement that persons found to be responsible for contamination of public or private drinking water supplies pay the cost of testing, monitoring, and substitution of temporary and permanent clean water supplies.

Second, there is a groundwater bill proposed by the Wisconsin Legislative Council Special Committee on Groundwater Management.3/ Formed in 1981, this Committee was charged with the duty of coming up with a comprehensive groundwater legislative package to deal with all issues related to groundwater contamination. It contains several components, which I will summarize quickly here. First, and most relevant to our

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3/ AB 595 (1983); WLCS 160/1 (1983).

discussion here, the bill would require that two types of groundwater standards be set, including standards for toxic substances. One standard would be called an "enforcement standard," the other a "preventive action limit" (PAL). The "enforcement standard" would be the level of a contaminant in groundwater where mandatory enforcement actions would have to be taken. These standards would be based on "federal numbers," such as EPA drinking water standards or guidelines.

Second, the bill would provide replacement drinking water supplies to citizens whose well waters are contaminated above "enforcement standards."

Third, the bill would contain an assortment of provisions for regulating particular sources of groundwater pollution, including pesticides, petroleum tanks, and other sources.

Time does not allow me to explain the details of this bill, and the many deficiencies I see in it for adequately dealing with toxic pollution of Wisconsin groundwaters. Suffice it to say, we are expecting a pitched battle in the coming months to either strengthen or weaken the bill's provisions. This brings me to what I think the Congress should and can do in conjunction with the Toxic Substances Control Act to aid Wisconsin in its most recent efforts to protect our own groundwater and to protect from toxic substances this Nation's most essential source of clean water for human, ecological, and economic consumption.

WHAT CONGRESS CAN DO UNDER TSCA--
TOXICS STANDARDS AND MONITORING ARE STILL NEEDED

I. Spur Adoption Of Drinking Water Standards.

First and foremost, there is a tremendous need among the States, especially Wisconsin, for the adoption of reliable drinking water standards establishing "maximum contaminant levels" (MCLs), against which to measure groundwater pollution. Although EPA is charged with setting these standards, including those for toxic substances, not nearly enough standards have been set. There is a need for Congress to ask why this is so, and to spur EPA into action.

Do not misunderstand me. These standards would not be intended, nor are current EPA drinking water standards intended, to condone the presence of a substance in drinking water nor to condone allowing drinking water of higher quality to degrade to established standards. Rather, they are established as goals to work toward when water is already of inferior quality and has been polluted. Still, the standards are indispensable to state standard setting and enforcement, such as under the rules and legislation that are now proposed in Wisconsin.

The standards-setting provisions in both the recently requested rules and the proposed Wisconsin groundwater bill are dependent upon the establishment of a "federal number." If no drinking water standard (MCL) exists, Wisconsin may look to "suggested no adverse response levels" (SNARLs), or acceptable risk levels for carcinogens, established at the federal level. If none of these "federal numbers" have been established, Wisconsin must resort to its own methods and means for establishing standards. To say the least, the State of Wisconsin, and I venture to say most other states, are not equipped to embark on any extensive standard-setting program for the hundreds of toxic pollutants that are already of public health and environmental concern.

In the event Congress can spur the development of these standards, the development of those standards should be bounded by the following public policies. First, it should be made clear that the adoption of standards does not condone the degradation of groundwater. Where cost-effective means exist to prevent the introduction of contaminants in groundwaters, there is no reason to subject the public to the risks, no matter how low, of the pollution, especially toxic substance pollution.

Second, two-tiered standard-setting approach similar to that described in the Wisconsin groundwater bill or in the "Assessment of Groundwater Contamination by Pesticides," prepared for the FIFRA Scientific Advisory Panel meeting of June 21-23, 1983, should be adopted. Each MCL for a substance should be accompanied by a still lower "warning level" or "preventive action limit" for the purpose of triggering mandatory monitoring and temporary or long-term action to prevent MCLs from ever being reached. In the area of pesticides, the EPA Office of Pesticide Programs suggests the "warning levels" be set at 10% of the MCL.

Third, if drinking water standards for toxic substances are going to be established by EPA, the authority must be exercised under TSCA to require the generation and submittal for review of toxicological data on chemicals and other information relating to who is manufacturing them, how the chemicals are used, how they are disposed, and what is their environmental effect. TSCA is the premier federal law for the gerneration and review of this kind of information on which drinking and groundwater standards for toxic substances must be based. This data and review under TSCA are valuable, if not indispensable, to the development of groundwater standards for toxics.

Fourth, coordination between bureaus and offices within EPA, including the sharing of toxicological and related data on toxic substances, is necessary for the development of groundwater standards. Particularly important is the need for sharing this data, not only within the agency, but between EPA and the States. Many States, including Wisconsin, should have access to that data when establishing or implementing public health or environmental protection responsibilities.

Fifth, ultimate groundwater standard-setting responsibility should be housed in the the EPA Office of Drinking Water (ODW), rather than being scattered among different offices and divisions depending upon the substances at issue. For example, while the Office of Pesticide Programs (OPP) must be allowed to continue generating information that would also be relevant in the setting of groundwater standards, that information should be available to ODW and be utilized by ODW in the establishment of groundwater standards for pesticides. Likewise, under TSCA, EPA's Office of Pesticides and Toxic Substances (OPTS) should be expected to share its information in the establishment of "no observable effect levels" (NOELs) for toxic substances with ODW and the States.

Sixth, Congress should make it clear that groundwater standards established by EPA constitute mandatory minimum standards which do not preempt the States from adopting programs that provide better protections from the risks of toxic substances in the groundwater than that provided under federal law.

And seventh, TSCA should make clear to manufacturers of toxic chemicals that the burden is on them to produce toxicological data and relevant studies to EPA before a chemical is placed in the marketplace. This is the conceptual policy framework for the regulation of pesticides, and there is no philosophical or reasonable basis on which to treat other toxic chemicals differently.

II. Monitoring Support.

Congressional support for adequate groundwater monitoring and testing of toxic substances in the groundwater is needed. Federal laws, including TSCA, do not provide the kind of monitoring that is needed to detect and regulate groundwater pollution by toxic substances. Both "ambient monitoring," to detect groundwater trouble spots, and "regulatory monitoring," to determine what specific responsive action should be taken, are expensive and expertise-intensive endeavors. States like Wisconsin are in constant need for legal, financial and expert support to carry out monitoring programs that have yet to be established to adequately deal with toxic groundwater pollution. And where responsible parties have been found for the toxic contamination of groundwater, the authority should exist to order those parties to pay the costs of the necessary monitoring to protect public health and try to remedy the problem.

CONCLUSION

In closing, I wish to state that in Wisconsin, although there is continuing dispute among interest groups, legislators, agency officials, and polluters over how regulation of toxic substances and other pollutants in our groundwater should be done, there is general consensus and I venture around the country, that regulatory action is needed to control toxic substance contamination of groundwater in this country. There is also a general consensus that once groundwater is polluted, it is probably polluted for decades, sometimes centuries, during which little, if any, remedial action can be taken. Although I can see that the costs of pollution prevention, as our public policy on groundwater, are formidable, I confidently state that the economic, ecological, and human costs of the alternative is beyond both our imaginations and our means to remedy it.

In this short time, I have attempted to summarize only a few of my thoughts that have evolved over the last several years on this subject. I offer to you, in a separate packet of materials, a more complete and comprehensive collection of facts and public policy discussions that have occurred and continues to occur in the State of Wisconsin on the groundwater pollution question. I offer this evidence of our efforts in the hope that you may develop a toxic substance groundwater policy that will carry us through the next several decades.

Once again, I thank you for this opportunity of addressing you today. I would be more than glad to answer any questions that you may have.

Respectfully submitted,

Thomas J. Dawson

THOMAS J. DAWSON
Wisconsin Public Intervenor
123 West Washington Avenue-Room 183
Post Office Box 7857
Madison, Wisconsin 53707-7857
608/266-8987

EXHIBITS

Partial Report of Final Data
Pesticides in Groundwater, September 13, 1982

Systemics	SNARL(5)	# Tested	# Positives	Max. (ppb)	2nd Max. (ppb)	Min. (ppb)	# Above Snarl
Aldicarb(4) (Temik) Union Carbide	10 ppb(3)	13	13	17	14	3	5
Disulfoton (Disyston) Mobay	1 ppb	13	12	100	90	8	11
Carbofuran (Furadan) Mobay	5 ppb	11	5	12	11	2	3
Herbicides							
Dinoseb (Dinitro) Dow Chemical	12.5 ppb	12	10	74	58	13	10
Sencor (Metribuzin) Mobay	25 ppb	11	3	6	4	2	-
Atrazine (AAtrex) Drexel	215 ppb	11	5	9	4	2	-
Linuron (Lorox) E.I. DuPont	62.5 ppb	11	1	3	-	-	-
Lasso(2) (alachlor) Monsanto	1000 ppb	11	0	-	-	-	-
Fungicides							
Bravo(2) (Chlorothalonil) Diamond Shamrock	150 ppb	11	0	-	-	-	-

1) Reported via letter dated September 13, 1982, Kenneth Kissler, EPA Beltsville Lab.

2) Reported together.

3) Advisory.

4) Aldicarb and Aldicarb Sulfone reported separately. These figures based upon Sum.

5) From Wisconsin DHSS

State of Wisconsin \ DEPARTMENT OF NATURAL RESOURCES

North Central District Headquarters
Box 818
Rhinelander, Wisconsin 54501
(715)362-7616

Carroll D. Besadny
Secretary

September 23, 1982

File Ref: 3300

Dear Well Owner:

In May of this year, a sample for pesticide analysis was collected from your well. Based upon the results of these tests, we recommend that you not use water from the tested well for cooking or drinking purposes. The water contains one or more pesticides in amounts greater than the guidelines recommended by health officials for long-term consumption.

We have attached a description of results and the recommended maximum containment levels for these materials.

Questions about these results can be directed to: Bob Martini, Department of Natural Resources, (715)362-7616 or Hank Weiss, Department of Health and Social Services, (608)267-7174.

Sincerely,

Bob Martini
Water Quality Planning
Group Leader

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
~~WASHINGTON, D.C. 20460~~
Building 306, ARC-East
Beltsville, Maryland 20705

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SEP 2[illegible] 1982

September 13, 1982

Mr. Kevin Kessler, Chief
Private Water Supply Section
Bureau of Water Supply
Department of Natural Resources
Box 7921
Madison, WI 53707

Dear Mr. Kessler:

We have completed the analysis and confirmation of approximately half of the water samples you previously sent us. A summary of the results is given in Table I. In addition to the specific pesticides of interest, we also screened all of the samples for organochlorine (example-BHC and methoxychlor) and organophosphate pesticides (example-parathion and malathion).

We are in the process of finishing the analyses on the remaining samples as well as running all samples for update (oxamyl) if adequate sample remains.

The QA procedures practiced in our laboratories are contained in the attached packet. You can identify information for the samples in question. Levels of fortification ranged from 1 - 100 ppb and unless routine recoveries range between 80 and 120% of the fortified level, QC on the methodology is examined.

All samples were extracted and analyzed using some portion of the attached methods manual. Determination and confirmation of residues were carried out using such instrumental techniques as EC/GLC, FPD/GLC, GC/MS and specific HPLC techniques. All residues were compared to known reference standards of the same compound.

The "Bottles" which we furnished for this study were "QC'd" in our laboratory prior to shipment and found not to give interferences in the analytical techniques used. The sensitivity of the methods used was about 1 ppb for all pesticides and metabolites (e.g. aldicarb sulfone).

It has been shown, and is well documented, that water samples stored in a frozen condition do not degrade pesticide residues. I feel that no loss of residues occurred in these samples, since they were always frozen until actual analysis.

You may note some differences between Table I and the verbal results I gave to Ron Becker. This is due to re-evaluation of the raw data prior to calculation. "Blank" water samples (Beltsville tap water) were run through all of our procedures and no interferences were encountered.

If you have any questions on any of the results or procedures, do not hesitate to get in touch with me.

Kenneth F. Kissler
Section Head
Analytical Chemistry
Section

TABLE 1

Pesticides in Wisconsin Water

ppb (parts per billion)

Sample number	Dinoseb	Oxamyl	Aldicarb sulfone	Sencor	Carbofuran	Atrazine	Linuron	Lassol Bravo	Aldicarb	Di-Syston	Organochlorine pesticide	Organophosphate pesticide
34-5-3-1	-	-	5	-	-	-	-	-	-	-	ND	ND
34-5-3-2	58		4	ND	ND	ND	ND	ND	6	20	ND	ND
34-5-3-3	ND		6	ND	ND	ND	ND	ND	3	100	ND	ND
34-5-3-4	ND		ND	ND	ND	ND	ND	ND	3	90	ND	ND
37-5-3-2	74		10	6	ND	3	ND	ND	ND	ND	ND	ND
37-5-3-3	13		ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
37-5-3-4	36		8	ND	2	2	3	ND	9	48	ND	ND
37-5-3-5	45		8	ND	ND	ND	ND	ND	6	45	ND	ND
37-5-3-7	29		4	4	12	ND	ND	ND	2	80	ND	ND
WA043001	26		6	2	11	4	ND	ND	6	43	ND	ND
WA043002	50		ND	ND	ND	ND	ND	ND	6	14	ND	ND
WA043003	48		6	ND	2	2	ND	ND	6	21	ND	ND
WA043004(A)	50		6	ND	8	9	ND	ND	7	8	ND	ND
WA043004(B)											ND	ND
PT82050301											ND	ND
PT82050302											ND	ND
PT82050303											ND	ND
PT82050304											ND	ND
PT82050305											ND	ND
PT82050306											ND	ND
PT82050308										30	ND	ND
PT82050309											ND	ND
PT82050310											ND	ND
PT82050311										30	ND	ND
PT82050312											ND	ND
PT82050401											ND	ND
PT82050402											ND	ND
A0043001											ND	ND
(D)P0043001											ND	ND
)P0043002	-		6	-	-	-	-	-	-	-	ND	ND

ND = Not detected less than 1 ppb

Blank - Sample still in progress

(-) Sample consumed for special analysis
e.g. special GC/MS screen.

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PAPER FOR ACS NOTES CONDITIONS LIKELY TO RESULT IN PESTICIDES IN WATER

A paper by four EPA scientists to be presented to the American Chemical Society (ACS) this summer lists chemical and field characteristics likely to result in pesticide contamination of ground water and notes positive findings of 11 pesticides in ground water samples from 13 states (See April 6, Page 13).

The pesticide characteristics: "Water solubility, greater than about 30 p.p.m.; K_d, less than 5, and usually less than one or two; K_{oc}, less than 300-500; vapor pressure, not that critical for volatile liquids which are soil injected (1,2-dichloropropane has a vapor pressure of about 40 torr at 20° C but has been found in ground water; it is soil injected); speciation; if negatively charged (either fully or partially) at ambient pH; hydrolysis halflife, greater than about six months; photolysis halflife, greater than three days; and soil halflife, greater than about two-three weeks."

The field conditions listed in the paper by four chemists in EPA: "Recharge, total precipitation and irrigation recharge $>$ about 10 in/yr.; nitrates, high levels in groundwater are indicative of pesticide groundwater contamination potential; soil profile, well drained and/or low organic matter content; and aquifer, shallow and unconfined."

When both the field conditions and physical characteristics are evident, "the potential for ground water contamination is high," the paper said.

The paper, "Potential for Pesticide Contamination of Ground Water Resulting from Agricultural Uses," was authored by Stuart Z. Cohen and Samuel M. Creeger of EPA's OPP; and Robert F. Carsel and Carl G. Enfield, Office of Environmental Processes & Effects Research, EPA, Athens, Ga. It will be presented before the Environmental Chemistry Division at the ACS meeting in Washington, D.C., Aug. 28-Sept. 2.

The 11 pesticides and levels found in water samples in 13 states, according to the paper:

Pesticide	States	Positive levels in p.p.b.
Alachlor	NB	0.4
Aldicarb (sulfoxide & sulfone)	NY, WI, FL, MO., AZ, ME, VA	5-50
Atrazine	NB, WI	0.3-3
Bromacil	FL	300
Carbofuran	NY, WI	1-50
Dacthal & metabolites	NY	50-700
1,2-dibromo-3-chloropropane	CA, AZ, HI, SC, MD	.02-20
1,2-dichloropropane	MD, NY	10-60
Dinoseb	WI, NY	20-60
EDB	GA, HI, CA	0.1-100
Simazine	CA	2

The officials' paper emphasized that the contamination measured and discussed was the result of normal agricultural use of the pesticides, not the result of dump site contamination.

The paper noted that pesticides registered more than 10 years ago are lacking "important environmental fate data."

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TOXIC SUBSTANCES CONTROL ACT OVERSIGHT

MONDAY, AUGUST 1, 1983

U.S. Senate,
Committee on Environment and Public Works,
Subcommittee on Toxic Substances and
Environmental Oversight,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:16 a.m., in room 406, Dirksen Senate Office Building, Senator David F. Durenberger (chairman of the subcommittee) presiding.

Present: Senator Durenberger.

OPENING STATEMENT OF HON. DAVE DURENBERGER, U.S. SENATOR FROM THE STATE OF MINNESOTA

Senator Durenberger. The hearing will come to order.

I apologize for the delay in arriving. When we were meeting at 9:30 I almost always got here at 9:30. When we meet at 10 o'clock I am 15 minutes late, and I do mean the apology seriously because I usually try. Since I am always here and you all are coming from other parts of the country, it isn't my business to inconvenience you, and so I do regret the 15-minute delay.

As all of the witnesses today know, most of you, I guess, were going to be here last Thursday, and because we needed to do a rather important markup on Thursday we had to put you off until this week. For that inconvenience I think it is also appropriate that you have our apology.

However, there is a good side to it, which I always look for. In our previous 2 days of hearings we have dealt with toxic problems in several different environmental media. We have heard from the Environmental Protection Agency, once in a formal presentation and then in a reactive presentation to our last panel on Friday. We have heard from people who are eminent and experienced observers and critics of EPA's programs to regulate toxic pollutants.

We have also heard from individuals from beyond the Potomac who face serious problems with toxic contamination on a daily basis. We have also received some specific suggestions during the course of those 2 days of hearings for improving the way the Toxic Substances Control Act works. I must say that I am impressed that it is a pretty good act, and there are those who believe that is because it was not passed by this committee but came out of the Commerce Committee. However, basically I, for one who wasn't around when it was designed and who has not had committee responsibility for implementing it, have been impressed by the basic framework that the act represents.

In a little while, after the panelists have finished their testimony, I am going to give each of the panel members a list of five of these recommendations, if you will, that we have tried to synthesize out of the first 2 days of hearings, and ask each of the panelists to briefly react to those recommendations, which in effect will expand the testimony.

Today we will hear testimony from a diverse panel which represents the chemical industry, environmental organizations, and public health organizations. I will call the eight members of the panel to come on up and arrange yourselves in whatever is an appropriate order. Dr. Jerry M. Smith will determine what the order it is going to be by going to one end of the table or the other.

Jerry Smith is director of toxicology for Rohm and Haas. Then there is Jacqueline Warren, Natural Resources Defense Council; Dr. Michael Scott, Mooney Chemicals, Cleveland, Ohio; Ms. Khristine Hall, an attorney for the Environmental Defense Fund; Dr. Jon Grunseth, vice president, government relations, Economics Laboratory in St. Paul; Dr. Allen Koplin, M.D., M.P.H., deputy commissioner for health for New Jersey; Mr. J. Ronald Condray, director of regulatory management, toxic substances, for Monsanto; and Mr. Jay Feldman, the National Coalition Against the Misuse of Pesticides.

We appreciate you all being here. We are going to proceed in the order that I called you. We are going to try to ask you to limit your oral testimony, to 6 or 7 minutes if you can. If you cannot, somebody here is going to stop you at 7 minutes into your testimony. Your formal written statements, will all be made part of the record. We will now proceed. Jerry, why don't you start first?

STATEMENT OF JERRY SMITH, DIRECTOR OF TOXICOLOGY, ROHM & HAAS CO., REPRESENTING THE CHEMICAL MANUFACTURERS ASSOCIATION

Mr. Smith. Thank you, Mr. Chairman.

I am Dr. Jerry Smith, director of toxicology, Rohm & Haas Co., representing the Chemical Manufacturers Association, CMA. We thank you for this opportunity to comment on the implementation of the Toxic Substances Control Act, TSCA.

The chemical industry believes that TSCA is working as intended by Congress, and the facts indicate that EPA is effectively implementing TSCA. Our industry is committed to complying with the intent and the letter of the law. Indeed, the industry has invested substantial human and financial resources to achieve these purposes. These efforts began before the passage of TSCA.

TSCA is a complex, detailed, and comprehensive statute that affects not only the chemical industry but many industries that use its products. CMA and its member companies have maintained an active interest in TSCA since Congress began considering toxic substances legislation in the early 1970's, and we supported TSCA's enactment in 1976. Furthermore, CMA along with other interested parties has worked to ensure that the act is implemented fairly and reasonably.

Two issues dominate the current discussion of TSCA: One, should TSCA require mandatory test data on new chemicals; and, two, can negotiated testing agreements be an effective approach for testing existing chemicals?

CMA believes that mandatory testing of new chemicals is not needed and is scientifically unjustified. Rather, it would be a poor use of limited resources and time, serving little useful purpose. Congress consciously rejected mandatory testing and chose the premanufacturing notification approach, specifying that all available test data and information be submitted. Furthermore, Congress gave EPA authority to require additional information when insufficient data is available for a reasoned evaluation of the potential hazard of a chemical. Congress designed this system to be flexible, recognizing that not all new chemicals would require testing nor present an unreasonable risk.

In the past year approximately 1,000 additional chemicals have entered the premanufacturing notification— that is, the PMN process. This brings the total to about 2,500 PMN's since the program started. Information contained in the PMN's or later supplied voluntarily by the manufacturer, combined with EPA's expertise and data base, has been sufficient to evaluate the potential risk of new chemicals. The facts as reviewed in CMA's written statement support the conclusion that the PMN review is working and does not need to be changed.

Those that advocate minimum testing for all new chemicals have cited the European Economic Community's sixth amendment, which requires new chemicals to undergo rigid base set testing. Those critics contend that TSCA should require a minimum testing scheme like the European system. However, they have failed to point out the differing approaches of the sixth amendment and TSCA which make it difficult to draw direct comparisons between the two laws. These differences are elaborated in our written testimony, and clearly point to the fact that the parts of one cannot be simply interchanged with the other without seriously upsetting the balance of each.

The Interagency Testing Committee [ITC] established by TSCA plays a major role in assisting EPA in identifying existing chemicals that should receive priority consideration for testing. The ITC activity is now succeeding because of the improved dialog between the committee, the agency, the public, and industry.

A major improvement in the existing chemical testing program is negotiated testing. The chemical industry supports EPA's use of negotiated testing programs to provide an enhancement to the overall testing activity. The value of negotiated testing programs has been demonstrated in the several programs negotiated, with testing now underway.

Using the negotiated testing approach, EPA conducts a dialog with those who know most about a chemical. Agency scientists meet with industrial scientists to obtain current and detailed information about the chemical, to determine what data if any is needed, and to work out the details of a testing program. The agency then solicits public comments and, following an evaluation of the public input, the agency concludes the testing agreement. The negotiated testing process identifies needed testing programs more effectively and efficiently than the rulemaking process.

As a toxicologist, I am comfortable with the use of structure activity relationship and exposure potentials for an initial evaluation of risk assessment. I believe that the flexible new chemical review and testing program and the combination of negotiated testing of existing chemicals with statutory safeguards provide the most cost-effective way to achieve good risk assessment and management.

A recent CMA survey—and we will provide the committee with a copy—of 112 companies demonstrated that our industry is taking their responsibility seriously. Approximately 90 percent of those companies routinely involve senior executives in developing and managing health and environmental affairs, and 1 out of every 55 employees is a health or environmental specialist.

In 1981, the 112 companies spent $138 million testing over 4,000 chemicals, and have testing facilities valued at more than $225 million. Various systems are used to communicate safety information. Almost all of these companies use the material safety data sheets. Almost all of the industry have hygiene and training programs to train their employees on how to avoid hazards chemicals may present.

In conclusion, the chemical industry believes, one, that TSCA is working as intended and should not be amended; two, that minimum testing should not be required for all new chemicals; and, three, that negotiated testing agreements are viable options to test rule development.

Thank you for hearing our comments. I will be most happy to answer any questions you have.

Senator **Durenberger**. Thank you very much.

Ms. Warren?

STATEMENT OF JACQUELINE M. WARREN, NATURAL RESOURCES DEFENSE COUNCIL

Ms. **Warren**. Thank you, Mr. Durenberger.

I have been working on TSCA implementation since the statute was being considered for passage. I want to begin by saying that unlike CMA, I don't think TSCA is working very effectively and I don't think it is working as it was intended. I was tempted to just be glib and say, "Just take the mirror image of what you just heard, and I will pass to the next speaker," but I am not going to do that.

I am evaluating TSCA on the basis of what the principal authorities in the statute are, as set out in the statute itself and also in the legislative history. The basic authorities—sections 4, 5, and 6—are very broad authority to require testing of chemicals, old chemicals or new chemicals; premanufacture screening of chemicals before they go into commerce, so that at least in theory the bad actors would be caught before they become an integral part of the economy rather than after and before the harm that they may do is actually done. The last authority is section 6, which is again a very broad and discretionary regulatory authority that empowers EPA to take a whole spectrum of activities to regulate exposures to a chemical, from the simple imposition of warnings or notices all the way through a complete ban.

Looking at what EPA has done under each of those provisions—the fourth authority that they have is to gather the data necessary to support the other three, and with that one I don't have a lot of problems about the implementation so far—I am very concerned about the way they are going on sections four, five, and six. As I said in my written testimony, looking at the EPA's record over the 7 years this statute has been on the books, it seems to me that TSCA has been more or less transformed into essentially a voluntary statute.

If you think back to the context in which TSCA was passed, it was one where we had had tremendous national concern expressed about asbestos and PCB's, PBB's, and a number of pesticides. There was concern that either the existing authorities didn't reach those adequately or that for one reason or another the chemicals were not being adequately evaluated before they went into commerce, and it was extremely difficult and quite costly economically and in terms of environmental and health damage to regulate them after the fact.

I will start with the premanufacture screening, even though I talked about them as four, five, and six. For section 5, again I said the purpose was to catch the bad actors before they go into commerce. A number of studies have been done, statistics have been gathered by EPA, and also most recently there was a report by the Office of Technology Assessment which shows that something like 50 percent of the new chemical notices are coming into EPA with no toxicity information whatever.

Now the representatives of CMA said it isn't necessary to mandate testing of all new chemicals, but it seems to me that some basic information is necessary on any new chemical before it goes into commerce. I am not calling for 2-year chronic cancer bioassays on every new chemical but I am saying, like all the rest of the civilized world is now saying, that a certain minimum amount of basic toxicity data is necessary for all new chemicals. The statute provides for exceptions from such a general requirement. The European system also provides for certain exceptions, and I don't have any problem with it.

However, I must say that to the extent that the agency looks at half the notices it receives and they contain nothing in them about the chemicals' toxicity, and the rest of the notices that come in only have some toxicity information—10 or 14 percent have environmental fate information—the agency has said and the OTA has said, and I agree that the amount of toxicity data that they are getting is really inadequate. As a result, the EPA must rely on structure activity analysis, which is the next best thing to actual data. It is information about other chemicals that are in some way like the chemicals that EPA is supposed to be evaluating, but it is not as good as data, actual data, on the chemical that they are evaluating.

EPA makes a judgment, and we hope their judgment call is right, because a large percentage of the 2,500 chemicals that have already passed through premanufacture notification are going into commerce and all we have is EPA's best guess as to whether at some time in the future they are going to come back to haunt us. We don't have actual data on those chemicals, nor do we have a tracking system in place by which EPA could look at the growth in the volume or type of use of those chemicals and say:

> We decided testing wasn't necessary previously on these because the proposed use was so small. The use is now bigger; the exposure is now bigger. We now want to know what the toxicity of this chemical is.

For that reason, we have been advocating in the House and I am advocating here today that a change in TSCA be made that authorizes EPA to devise a scheme of premanufacture testing for all new chemicals unless they are otherwise exempted. I would certainly leave room for the flexibility to exempt various new chemicals from part of that testing scheme or all of the scheme.

EPA is looking at premanufacture exemptions. They have come up with a proposal that would exempt 50 percent of all new chemicals from premanufacture notification. I think I would be more comfortable with that approach if I thought that for the other 50 percent, we are going to have the data for EPA to do a scan on them, because by definition those are presumably of higher potential risk because the ones that would be exempted pose presumably lower potential risk. However, we don't have the other part of the program. The European system has testing but it also has exemptions, and those new chemcials that aren't exempted do have to be tested. I have gone into greater detail in my written testimony on the PMN program, and Ms. Hall is going to speak to the European scheme as well in her testimony.

I would like to say a word about voluntary testing. TSCA is a regulatory statute. It was enacted at a time when national attention was raised about the IBT testing laboratory scandal. We are at a time right now when the IBT scandal is in the newspapers again. The statute provides that if the Administrator of EPA finds that either there are insufficient data on a chemical or has other reason to be concerned, or the Interagency Testing Committee, a group of experts created for the purpose, says, "These are the chemicals that ought to be considered for testing first," the agency is required to put out a testing rule which prescribes the protocols, uses notice and comment rulemaking, is enforceable, has deadlines for completion of the testing, et cetera.

Now, 7 years later EPA has not put a single testing rule out. They have received 64 recommendations from the Interagency Testing Committee for testing of high priority chemicals. I just read EPA's recent report, "Priorities and Progress." They say, "We have dealt with the backlog; we have dealt with 64 of these"—but there is not one single testing rule for any of them. The Agency has proposed rules; there have been rules proposed for years, but they never finalized them, and instead they have a series of voluntary negotiated agreements.

I don't have any problems theoretically with negotiated agreements for testing, but for the priority chemicals that the experts have said, "These are to be tested first," the statute set up an action-forcing mechanism for EPA to deal with the recommendations in 1 year, to get the testing started. The agency has taken, what I consider an unconscionably long time to deal with the expert's recommended chemicals, and the only testing that is going on is under these negotiated agreements which are not enforceable.

They don't have any deadlines. The public is peripherally involved in the process. EPA cannot even enforce them; it is not even a contract with the Agency.

Senator **Durenberger**. You are going to have to move to your conclusion, I'm afraid.

Ms. **Warren**. OK. My conclusion is, at least for the priority chemicals, that if EPA wants to negotiate what the testing scheme should be, then the Agency should incorporate that agreement into a rule that puts the deadlines in, makes it judicially reviewable, and triggers all of the related statutory provisions, which a testing rule was intended to trigger. When you have a regulatory statute with all the provisions interrelated and keyed to action by rule, if you don't do it by rule it completely renders inoperative all the other sections.

I will pass over the section 6 history, in which my testimony is very clear about the small number of chemicals that have been dealt with by regulation.

I just wanted to mention one other point, which has to do with the breadth of the confidentiality protection that the statute offers. TSCA offers broader confidentiality protection than just about any other environmental statute. I attached some sample PMN notices from the Federal Register at the end of my testimony. If you take a glance at those, you will see what I am concered about. Those are supposed to provide an apportunity for public comment on a new chemical. But this is what the notice says: name of the chemical: confidential; company: confidential; proposed use: confidential; volume: confidential; environmental release: confidential; disposal method: confidential; toxicity data: none submitted.

In my opinion, there is no point to that kind of public notice. There is nothing anybody can do with it, and it effectively precludes any sort of public involvement in the premanufacture notice process. Confidentiality should be limited to truly trade-secret information, so that if someone is devising a new way to dispose of PCB's, it cannot be claimed confidential. The amount of a fine should not be confidential. A notice to EPA indicating that bone cancer has been caused by an existing chemical that people are working with should not claim the name of the chemical confidential.

I have serious problems with the actual effectuation of the goals of TSCA, when these kinds of obstacles are in the way.

Thank you.

Senator **Durenberger**. Thank you.

Dr. Scott?

STATEMENT OF MICHAEL J. SCOTT, GENERAL COUNSEL, MOONEY CHEMICALS, INC., REPRESENTING THE SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, INC.

Dr. **Scott**. Mr. Chairman, I am Michael J. Scott. I am general counsel of Mooney Chemicals. We are a small manufacturer of specialty chemicals based in Cleveland, Ohio. Today I am representing both Mooney and the Synthetic Organic Chemical Manufacturers Association, which is a nonprofit trade association representing over 100 chemical companies, the majority of which are small companies.

My remarks today focus on actions taken by chemical companies like mine to comply with TSCA, on the costs of this compliance, and on the extent and limitations of information submitted pursuant to the requirements of TSCA. Let me briefly summarize the five points in my testimony today.

First, I would like to start with a little discussion of Mooney Chemicals and how we have been involved with TSCA. We have gone through the inventory reporting, recordkeeping requirements under sections 8(a), 8(b), and 8(e), and we are also currently involved in a Section 4 process.

Second, I would like to discuss how the PMN requirements have had a significant adverse impact on small business innovation. The type of innovation conducted by small companies such as Mooney often involves only a slight change in an existing chemical substance for use by a customer, usually in small volume. About 60 percent of the small business PMN's are for chemicals with production volumes less than 10,000 kilograms per year. Many of the small volume innovations have a gross revenue—not a net revenue—that is several times less than minimum cost of a PMN submission. The result of these PMN requirements has been to inhibit innovation by small companies like Mooney Chemicals.

The third point in my testimony is that because of this cost burden of the PMN program, EPA should promulgate a final PMN exemption rule for low-volume and site-limited, intermediate chemicals. Unfortunately, in the past EPA has defined small manufacturers exempt from recordkeeping and reporting under Section 8(a) in a number of different ways, without any consistency whatsoever.

It is unwarranted for EPA to burden small companies with the necessity of examining each rule to determine whether or not a firm is small for purposes of this particular rule or whether they are somehow within the rule. I would ask for this subcommittee's help in encouraging the EPA to promulgate a final rule which would define small manufacturers in a consistent manner.

Last, I would like to comment on the extent and limitations of information which is being submitted under the PMN process. I would like to touch on two recent studies which addresses the issue of the adequacy of the PMN data. These are discussed at length in my prepared statement.

Having introduced these as major points, I would like to describe Mooney's experience. We have complied with the 8(d) inventory. We have set up reporting systems for section 8(a) and section 8(e), and at present we are currently responding to an ITC recommendation regarding three chemicals which represent a large part of our business and, I might say, has required a major investment of our managerial time and technical time.

With regard to section 5, despite a history of innovation in our company we feel that the PMN requirements have restricted the extent of our research activities, with the result that we have not yet had to file a PMN for a new substance. Now one of the basic issues in the operation of the PMN program is whether and to what extent the PMN requirements have had an impact on the rate of innovation by small companies. It has had an adverse impact on Mooney chemicals, and several studies of the PMN program suggest that this impact has been felt by small business generally. I think we will hear later on from some of those other small companies.

The type of innovation which is conducted by small chemical manufacturers most often involves a slight change in an existing substance for use by an individual customer in small volume. In other words, for Mooney we are in a narrow niche of technology and our innovations are going to come somehow close to that narrow area of technology.

Studies conducted by EPA of PMN's submitted by firms with less than $100 million in sales indicate that 62 percent of small business PMN's are for production volumes of less than 1,000 kilograms per year. Thirty-one percent of small business PMN's are for chemicals with estimated production volume of less than 1,000 kilograms per year.

Therefore, using these figures, a simple example will illustrate why PMN requirements so greatly influence small business innovation, and thus why the number of PMN's submitted by small business has been so low. Take a high price, the highest price for chemicals considered in the regulatory impact analysis of the PMN rule. That would be $2 per kilogram.

Now a substance which is produced in the 1,000 kilogram quantities would result in $2,000 of gross revenue. EPA's own figures conservatively estimate that the final PMN rule will cost between $5,000 and $12,000 complete, and dividing the one into the other, it would be from two to six times the expected gross revenue to complete a PMN submission than could be expected from that product in its initial year.

Therefore, in essence, the costs of submitting a PMN are very high in relation to the revenues, especially for low-volume chemicals in the initial stages of commercialization. Clearly only very high-priced, low-volume chemicals could support these types of regulatory costs.

Let me move into the area of the need for a PMN exemption. In light of these costs of compliance with the PMN program, I believe EPA should promulgate a final PMN exemption for low-volume chemicals and site-limited intermediates. SOCMA supports the general approach taken by the agency in the proposed rule, and we strongly support an abbreviated PMN exemption process for very low-volume chemicals produced in quantities of 1,000 kilograms per year or less, because this measure would particularly benefit small business and, we feel, without any significant risk to society or the environment.

In the past, in another area, one of the major concerns with EPA's implementation of TSCA has been the narrow rule-by-rule manner in which the agency has defined small manufacturers for purposes of the statutory small manufacturer exemption from routine reporting and recordkeeping requirements. EPA has used at least four different definitions, to my knowledge. This inconsistency is a great problem for small business in determining what rules apply and what rules don't. For example, Mooney Chemicals would qualify under some definitions and not qualify under others.

Last June EPA issued a proposed definition of small manufacturers for use under section 8(a), "Recording and Recordkeeping." It is important to small business that this rule become final, and we would ask your help in encouraging EPA to do so. A study carried out for EPA as part of the rulemaking indicates that the rule would reduce the quantity of information submitted to the agency by only 10 percent. However, the total cost to small manufacturers would be reduced by over 60 percent. I believe the benefits of this type of a rule are clear and the risks would be minimal.

The last point that I want to address regards the adequacy of the PMN requirements. A question has come up whether the PMN data requirements in the statute are sufficient to allow EPA to perform an adequate health and environmental evaluation of a new chemical. There are two recent studies, one by the OTA which you have heard of in prior testimony, and another by ICF, which is the regulatory impact analysis on new chemicals under section 5 conducted by ICF. Both of these studies have focused on the issue of the PMN information submitted on new chemicals.

With regard to the OTA study——

Senator **Durenberger**. Are you getting to the end?

Mr. **Scott**. Yes, I will be wrapping up here.

I believe that the OTA methodology used does not support the type of conclusions that they draw. Contrasting that with the ICF study, which used a more appropriate methodology, this study indicates that information required by the final PMN form is sufficient to identify the risks with which the agency is concerned.

I have the ICF study, and I will try and conclude by saying that in this particular analysis, contrary to the OTA study, the question was asked: Of the chemicals that EPA had isolated for review, those that EPA had kicked out of their PMN program as suspect, ICF went through and looked at those and asked the question, would the regulatory outcome be different under a different form? Under, say, mandatory testing, would the regulatory outcome be different than under the current form? The answer that they give, from my reading of it, is that no, the current PMN requirements are adequate and give the agency the authority to prevent risks.

Thank you.

Senator **Durenberger**. Thank you very much.

Ms. Hall?

STATEMENT OF KHRISTINE HALL, ATTORNEY, ENVIRONMENTAL DEFENSE FUND, WASHINGTON, D.C., ACCOMPANIED BY ELLEN K. SILBERGELD, SENIOR TOXICOLOGIST, EDF

Ms. **Hall**. Thank you.

I am accompanied this morning by Dr. Ellen K. Silbergeld, who is EDF's senior toxicologist.

I would like, first of all, to endorse the remarks made by Jackie Warren from the Natural Resources Defense Council. EDF also agrees that the basic promise of the Toxic Substances Control Act, to remove dangerous chemicals from the environment and prevent new chemicals from becoming widespread, has not been fulfilled. In part this is because of problems in the statute, and in part it is because of EPA's hesitant implementation of the statute.

One of the main problems, as indicated by Ms. Warren, is the lack of data for screening new chemicals. The express goal of TSCA as expressed in section 2, of adequate data provided by the manufacturers of chemicals, is largely unmet. The pittance of data that EPA now receives under the section 5 program just does not allow EPA to make a fair determination as to whether an unreasonable risk is posed to health and the environment.

The SAR process that EPA uses as a substitution, as a way of getting around the lack of data, is inadequate for making determinations as to the risks posed by these chemicals. In the first place, the SAR process as used by EPA does not even meet the standardized form that is used widely in other toxicological entities.

Second, the adequacy of SAR as a means of evaluating chemicals depends on having a reliable data base, a full data base. Even in those areas where we have the most information—on carcinogenesis—the data base is inadequate for making judgments, for comparing new chemicals to old chemicals. That is to say nothing of the very large gap that we have in the data base on neurotoxicity and reproductive effects.

Third, very small changes in chemical forms can lead to very big changes in toxicity. Thus, analogizing new chemicals by structure similarity to old chemicals may lead to wrong conclusions. By relying on SAR, ERA is really making guesses about the risks posed by chemicals. Although it may catch a few dangerous chemicals, it does not catch the majority of chemicals because it says nothing valuable about the majority of chemicals.

We do not accept SAR as a basis for judging toxicity of pharmaceutical chemicals or pesticides, and it should not be used as a basis for judging the toxicity of new chemicals under this program. We strongly urge you to closely examined the adequacy of SAR as the basis for the new chemical program.

As Ms. Warren mentioned, the European countries now do require a base line set of data to be submitted with new chemicals. The fact that the European Community is far ahead of the United States in this area suggests the underlying value of international cooperation in this important area.

In fact, there is a far-reaching program of international cooperation and harmonization underway in the Organization for Economic Cooperation and Development, an alliance of 24 developed countries ranging from Japan and Australia to most of the European countries, the United States and Canada. The toxic chemical program of OECD has been put into place in order to share precious information on the toxicity of chemicals, to avoid transnational pollution incidents, and to prevent nontariff trade barriers.

The United States was once a leader in the efforts of OECD's chemical program, but that is no longer the case. The fall from leadership came with the bruising battle the past 2 years over what is known as MPD—the issue of base line data being required for testing of new chemicals. Urged by the American chemical industry to oppose any steps toward requiring base line data, the Reagan administration suddenly reversed position in 1981 and put the brakes on the efforts of OECD to reach agreement on harmonizing testing of new chemicals.

The unusual result was that the United Kingdom and France, notoriously countries with weak environmental programs, had a stronger position on environmental protection than the United States. The result also was a high degree of alienation between the United States and several of its traditional allies on this particular topic.

We have much to learn from European countries and from the Asiatic countries, just as they have much to learn from us Japan has a very sophisticated system of toxic chemicals evaluation, for instance. We recommend that Congress examine the EEC system and the OECD work on base line data. The U.S. is fundamentally out of step with what the rest of the world is doing in this area, and we question whether this is appropriate.

OECD also has other toxic chemical programs of note and of interest to the TSCA program. Notice of exports is one that has also been controversial. There is a new program just beginning on evaluating existing toxic chemicals, identifying them for testing and for further regulation. We hope that the United States resumes a position of cooperation and leadership on these programs, because we think they have a lot to say about how our domestic program should be carried out.

Also very briefly, we are concerned with how EPA has chosen in many instances to ignore the ITC. One means of doing that, one excuse for doing that, relates to exposure data. They have claimed in many instances that though the chemicals may be important, the exposure information does not justify further regulation.

We are concerned because at many times the exposure information is inadequate. The PMN process as presently constituted and the other means of gathering data on exposure just do not give us enough information to make reliable conclusions about exposure. In addition, much of it is confidential. This area of exposure is very important. EPA must evaluate scenarios as well as molecules in determining risk to human health and the environment.

In addition, EPA has chosen to ignore some important areas of toxicity. I cite as an example their overruling of the ITC's recommendation on pyridine, which is a well-known neurotoxin.

Finally, we would like to urge that TSCA and the Office of Toxic Substances be more fully integrated with the rest of EPA's program areas. Typically, people in EPA who know something about air pollution don't know what is going on with water, and the activities of the Office of Toxic Substances are not well integrated into other program areas.

Dioxin is a prime example of why this is important. It doesn't make sense to lower concentrations of dioxins in products, for instance, only to have the removed products show up in our air and water or ground water from solid waste dumps. Likewise, the growing area of municipal incineration is leading to more and more dioxin being put into the environment, both through the fly ash and through air emissions.

What is needed for priority pollutants is to have an integrated approach. We suggest that the Office of Toxic Substances and the authority of TSCA are one way of pulling that together.

This also ties in very well, I think, with an amendment that was voted out in RCRA reauthorization last week, where it was recognized by the committee that certain substances should not be in landfills. The PMN process and the existing chemicals process provide a good method of screening chemicals, not only for their introduction into the environment and exposure in the workplace and exposure to consumers, but also potentially for evaluation on how these chemicals should be disposed of or their byproducts disposed of in the final instance. There is not enough integration between the Hazardous Waste Office and OTS to insure that, when a new chemical is put on the market, we know where it is going to finally end up in disposal. We think this needs a lot more work.

Thank you very much.

Senator **Durenberger**. Thank you very much.

John Grunseth?

STATEMENT OF JOHN GRUNSETH, VICE PRESIDENT, GOVERNMENT RELATIONS, ECONOMICS LABORATORY, INC., REPRESENTING THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, ACCOMPANIED BY CHARLES LENTZ, DIRECTOR OF HEALTH AND ENVIRONMENTAL SCIENCES, DOW CORNING CORP., MIDLAND, MICH.

Dr. **Grunseth**. My name is John Grunseth. I am first vice chairman of the Chemical Specialties Manufacturers Association, and vice president, public affairs, Economics Laboratory. I am accompanied today by Mr. Charles Lentz, director of health and environmental sciences, Dow Corning Corp.

CSMA has a membership of nearly 400 firms, a number of which are small businesses engaged in the manufacture, formulation, distribution, and sale of chemical products for household, institutional, and industrial uses. Mr. Chairman, we welcome the opportunity to provide our comments to your subcommittee on the reauthorization of TSCA.

We respectfully recommend that TSCA be reauthorized for 2 or more years without change or modification, so that the careful balance originally constructed be retained. TSCA is unique among the numerous health and environmental statutes in its breadth and scope and purpose. TSCA was essentially designed to provide environmental protection in areas not addressed by other statutes. In writing this legislation, Congress perceived that TSCA should have the broadest and most flexible authority to require anything from labeling to the banning of a substance.

In establishing TSCA, Congress created a different system than those under such statutes as FIFRA and the Food, Drug, and Cosmetic Act. Under TSCA, Congress initiated the broadest possible program directed at the full range of chemicals, and gave the EPA an extensive scope of powers not found under other statutes. Throughout the legislation Congress sought to create a delicate balance that would evaluate the risks and benefits, as well as consider the environmental, economic, and social impact of any action the administrator takes or proposes to take under this act.

Congress gave EPA the authority to assess new chemical substances before their commercial manufacture. TSCA also provides authority to gather information on existing chemical substances and regulate the manufacture, processing, distribution, and disposal of new or existing chemicals. Further, the agency can also require testing. This authority was essentially designed to fill the gaps created by other existing statutes.

To avoid overlapping regulation, Congress intended that EPA would invoke TSCA to control existing chemicals only where a substance presented an unreasonable risk of injury to health or the environment, or created an imminent hazard not adequately addressed under other health and environmental statutes. TSCA also directs the EPA to avoid requirements that would unduly impede technological innovation.

TSCA's impact on industry has been widespread and significant, and important changes in industry practices have accompanied TSCA's implementation. Regulations contained in TSCA sections 4, 5, 6, and 8 in particular have placed significant burdens on industry.

TSCA programs generated considerable controversy at the onset, as the agency proposed a number of regulations that were scientifically unsound, legally questionable, impractical, or unduly burdensome. These difficulties are being addressed, however, and as a result the EPA's present TSCA programs, while not satisfactory in all respects, are achieving the act's objectives to protect human health and the environment.

Although we are not seeking any modifications of the TSCA statute, we would like to take this opportunity to discuss, based on our experience, some of the concerns we have with its implementation. The section 5 provisions have led to the implementation of a premanufacturing notification process, or PMN's, and a system of evaluating new chemicals.

When TSCA was enacted, Congress avoided the imposition of rigid health and environmental testing requirements under section 5 for very good reasons. Mandatory testing requirements would, first, be too rigid and provide too little flexibility in exercising scientific judgments. Second, they would result in inappropriate and unnecessary testing. There are also other problems which we have submitted for the record in our written testimony.

TSCA's premanufacture notification requirements have been generally functioning most effectively for the last 3 years. It would be unwarranted and counterproductive for the United States to abandon a regulatory system that has demonstrated effectiveness, in favor of an unproven, across-the-board "base set" approach.

In balancing this activity, section 5 of TSCA requires the EPA to review the health and environmental effects of all new chemicals before their commercial introduction. Under section 5(e), the EPA can delay or prevent the manufacture or use of new chemicals pending the development of test data or other information. Section 5(f) authorizes EPA to restrict manufacture or use where a new chemical presents an unreasonable risk of injury.

After a chemical completes PMN review, TSCA provides the EPA with wide-ranging authority for monitoring and controlling the chemical throughout its commercial life cycle. Production, use, and health and safety data, for example, can be collected under provisions of section 8. Testing can be required under section 4, and control measures can be imposed under the "significant new use" provisions of section 5, the rulemaking provisions of section 6, or the "imminent hazards" provision of section 7.

EPA has found that a great majority of new chemicals it reviews raise minimal health or environmental concerns, and can enter the marketplace without restriction. The agency has taken prompt action on those few occasions where a new chemical raises sufficient health or environmental concerns to warrant control.

For example, it has issued orders under section 5(e) prohibiting the production of or otherwise regulating 18 new chemicals pending the development of test data. PMN's for several other new chemicals have been withdrawn in the face of EPA action. In approximately 60 cases, manufacturers have volunteered to suspend the PMN review period while developing additional data or, at the EPA's request, have instituted measures to reduce exposure or otherwise limit risk.

These statistics confirm that a high percentage of the chemicals that enter the PMN process pose low risk, and that the process is effectively identifying those few chemicals that warrant closer attention. A number of small businesses, however, have incurred problems with the PMN process. I would like to specifically urge that your subcommittee initiate a complete examination of the problems small companies face in complying with TSCA.

The provisions of TSCA have restricted the ability of small chemical companies to take advantage of their special capacity for innovation and quick response to immediate or specialized needs of customers, which has been an important basis for small company competitiveness. TSCA has reduced small company innovation by imposing substantial fixed costs related to PMN submission, data generation, recordkeeping, and reporting.

To address the impact of TSCA on innovation within the chemical industry, the Chemical Specialties Manufacturers Association commissioned an independent consulting firm to conduct a comprehensive analysis of the act's effect on the chemical specialties industry. Mr. Chairman, we would like to submit a copy of this study for the hearing record.

One hundred member firms provided data for this study, which covers a 5-year period from 1976 to 1981. Results of the study indicate that a major impact of TSCA has been due to its requirement, in effect since 1979, that firms file notification with the EPA 90 days before the manufacture of any new chemical substance. Specifically, the study showed that the implementation of TSCA resulted in a decline of more than 25 percent in new substance development within the chemical speciality industry. Smaller businesses are most severely affected, especially those with less than $50 million in sales. The decline in innovation for these firms was 85 to 90 percent.

The study also shows that much of the decline in chemical specialties innovation is directly attributable to the cost of filing the TSCA-required premanufacturing notice. The CSMA study also indicated potential for several long-term impacts on the chemical specialty industry should this innovation rejection trend continue. These include increased failure of small businesses, serious lessening of competition, and a loss of economic productivity and social benefits due to a decrease in innovation.

Although the loss of innovation is a significant problem for small manufacturers, the existing burden of reporting and recordkeeping under section 8 of TSCA also has a disproportionate impact on small businesses. It is possible to reduce these requirements without jeopardizing the information needed to make a fair risk analysis. There needs to be a balance in the regulations that addresses the limited resources of small business.

In explaining section 8(a), small business exemption language, the House report states:

> Because reporting and recordkeeping requirements under section 8(a) may impose a particularly heavy burden on small manufacturers or processors, the committee provides an exemption for such reporting and recordkeeping for small manufacturers or processors.

Senator DURENBERGER. You are moving to your conclusion, right?

Dr. GRUNSETH. In conclusion, we would urge the subcommittee to review the recordkeeping provisions for small businesses. Congress recognized, in passing the Regulatory Flexibility Act in 1980, that small businesses have long shouldered the same burden of Federal regulations as their larger competitors but with fewer resources.

Recently the EPA has taken several commendable steps and measures which address small business problems under various TSCA amendments. The TSCA Assistance Office provides much-needed aid in understanding and complying with the requirements of TSCA. Several of our members have used the PMN Field Technical Service Office for small businesses, which enabled them to successfully file PMN's.

Many of the smaller firms, who depend on this technical support to comply with TSCA requirements would be placed at a great disadvantage without it. CMSA strongly urges you to continue to support the activities of the TSCA Assistance Office.

While there has been progress in several matters of concern to small business, more needs to be done if small chemical companies are to continue as viable members of the chemical specialty industry. We hope that these and other previously mentioned concerns with TSCA can be resolved by working with the administration.

Mr. Chairman, that concludes my testimony.

Senator DURENBERGER. Thank you very much.

I will have to say to the last three witnesses that you will have to keep your conclusions to three sentences. That was a very long conclusion, as were a couple of others.

Our next witness is Dr. Allen Koplin of New Jersey.

STATEMENT OF DR. ALLEN KOPLIN, DEPUTY COMMISSIONER FOR HEALTH, NEW JERSEY STATE DEPARTMENT OF HEALTH, REPRESENTING THE AMERICAN PUBLIC HEALTH ASSOCIATION

Dr. KOPLIN. Thank you, Senator.

I want to thank you for the opportunity to appear here today to present the testimony of the American Public Health Association on the Toxic Substance Control Act. I think you face a rather unenviable task in reviewing this legislation, because obviously you are being presented with diametrically opposed points of view that you have to resolve, and I don't propose to provide any magic formula to help you accomplish that today.

I think there is an interesting aspect coming out of this testimony, however, and that is the fact that on the one hand we have those being regulated satisfied with the regulatory activities that are being conducted, and others with what I would consider a more public health point of view who are usually in favor of controlling health hazards and who engage in other kinds of health activities, on the side of not being satisfied with the regulatory activity that has been going on. Perhaps that says something about the administration of TSCA.

The American Public Health Association reprecents 50,000 public health workers throughout the United States, and has a critical stake in the identification and control of toxic substances in the human environment. It is our particular concern that many of the chemical products to which we are exposed from time to time represent the major public health threat of this decade, and it is our position that action is needed now to insure the effective implementation of this law.

I appear today also as a representative of the State of New Jersey, where chemical production, distribution, and storage facilities are as highly concentrated as in any State in the Nation. Parenthetically, 651 of the top chemical dumps exist in our State, and we are striving to continue the deceleration of cancer death rates, whose magnitude probably bears a direct relationship to our industrial development, especially in chemical and drug manufacture. New Jersey now has the highest mortality rates for bladder cancer in white males, which undoubtedly represents the effects of chemical exposures of 20 to 30 years ago.

These human chemical exposures make it imperative that the TSCA legislation be administered in such a manner as to help New Jersey and other industrial States to know more clearly where they stand in terms of toxic and mortality risks and to prevent further undesirable effects from new products. The TSCA proposal was intended to be enacted in 1970, when a whole host of acts were passed which came to grips for the first time in this country with problems the environment. As you know, EPA, OSHA, the Federal Hazardous Substance Labeling Act, the Coal Mine Health and Safety Act, the National Environmental Policy Act, all these laws were passed at that time, and we had high hopes for EPA and OSHA to accomplish a great deal.

However, it took about 6 years before the TSCA act was passed, and I believe this was kind of a linchpin of data that everybody else needed in most of these other activities. Now that they have identified 50,000 significant substances of potential toxicity in commercial use and have a preventive strategy, so that the approximate 1,000 new chemicals added annually would be tested before general use, I think we are in a position to pinpoint, avoid, and perhaps remove the most dangerous products.

The TSCA act, passed in 1976, promised to accomplish these goals, but I can tell you from our experience in New Jersey, and the experience elsewhere, that if it had in fact succeeded, perhaps the people of Times Beach, Newark, and elsewhere would have been aware of the presence of dioxin as a byproduct in the manufacture of 2,4,5,T and 2,4,D. Perhaps the public health authorities in our State and other States would have been able to respond more promptly to the questions of the population who have wanted to know why has it taken so long to tell us in Newark that this hazard exists and that it has been there for the last 15 years.

The law has several strong features. They have been enunciated. The inventory which I mentioned, and the Interagency Testing Committee to identify the high priority toxic agents in terms of cancer, birth defects, chromosomal changes, and how they ought to be tested. The act contains provisions to ban the sale of high-risk products, requirements for labeling, public information, funds for State grants—which no one has mentioned, but which we certainly have put to good use in New Jersey—and so forth. However, the act has not fulfilled all of the fond hopes that these provisions originally intended.

Others have discussed the problems of testing, the voluntary agreements and the exoneration of many of the compounds reported to EPA without any particular testing rules, and so forth. I won't go into that. I do know that the information required for new products has probably been more sketchy than necessary, lacking in some of the most essential ingredients, such as how the particular substance may be toxic. I do know the public has not been informed adequately, as I said a while ago, and I really don't know how many substances have been banned as a result of this act. I think the number is probably not very large. As I say, there has been some problem of financial support, not only in terms of State grants but funding for the EPA and the staff needed to carry on the functions mentioned.

I would like to add something from the public health point of view, and that is this: Another basic defect in the law is the lack—or a basic defect in the law, I should say—is the lack of reliance on public health and epidemiologic expertise, especially that already present in the U.S. Public Health Service. The testing of toxic substances often requires human case control studies, and while some producers of chemicals have employed epidemiologists and can perform these functions, most likely the vast majority of the chemical industry does not possess that kind of expertise.

Therefore, in summary, I think we have a good bill which is in the public interest, which we in the public health profession support in its basic provisions, but which through inadequate administration and financial support has really been thwarted in its basic intent, which is to protect "* * * human beings and the environment being exposed each year to a larger number of chemical substances."

I have some recommendations based on what I believe and what the APHA believes. Before I mention them, I want to take you out of the scene in Washington and back to the grassroots where you live and I live, and to give you the flavor of what we are going through in a State like New Jersey. I think that will explain some of the strong feelings I am about to express.

First of all, I think everyone that has the same point of view that I have expressed here feels that the act needs to be enforced as intended under the Environmental Protection Agency, but I think something more has to be done to reinforce this responsibility, through resolution of Congress or through other means available.

Second, I think that part of the problem we are dealing with is that the Congress needs to reaffirm, in relation to toxic substances, that human health needs shall take precedence over commercial objectives. That might sound rather strange, but that is one of the basic difficulties we have with this kind of legislation. The story in Takoma, for example, explains that rather well.

Third, the public health implications of the legislation need to be strengthened through administrative actions, as follows: I think the Assistant Secretary for Health of the Department of HHS, for example, and the Public Health Service staff should be required to play a more effective policymaking role. We need to talk about the health effects more than the other kinds of situations which we have been discussing. Second, I think the adequacy of epidemiologic methods for substance testing need to be emphasized.

I think, frankly, that the EPA when it was created represented a fracture of public health activity in the United States. Most of the people who moved into EPA in the early days and to the State counterparts came from State health departments. There is no reason why the EPA should remain fractured. It is my opinion that eventually the EPA should be merged, for the public health reasons I outlined, with an agency like the U.S. Public Health Service, to reestablish the inclusion of all environmental health programs as part of the mainstream of basic public health operations.

Finally, I am motivated by this last recommendation to comment on the Takoma, Wash., alternatives that have been proposed: That is, either suffer the consequences of your work in this copper smelting plant or lose your job, a choice which is unforgivable for anyone to contemplate in the United States. However, suppose that happens to be a problem. Suppose it should prove that human protection against the risk of toxic substances places an inordinate social and economic burden on a producer or a community, as I say, in Takoma.

More effective legislative remedies may be necessary for situations of this kind. When a chemical product is vitally needed—and certainly I am not denying that many of them are—under such conditions consideration should be given to public intervention, through grants, loans, other Federal aid, which is not unknown in this country, or if necessary in the public interest such an enterprise may need to be converted to a publicly held corporation. This would be the last resort remedy to insure the availability of needed products, while at the same time protecting humans against toxic exposure despite the economic situation affecting a particular producer or a community.

Thank you very much.

Senator **DURENBERGER**. Thank you very much.

Mr. Condray?

STATEMENT OF J. RONALD CONDRAY, DIRECTOR, REGULATORY MANAGEMENT, TOXIC SUBSTANCES, MONSANTO CO.

Mr. **CONDRAY**. Thank you, Mr. Chairman.

Good morning. My name is Ron Condray. I am employed by Monsanto Co. in St. Louis, Mo., and have corporate responsibility for regulatory management of the Toxic Substances Control Act.

Monsanto produces a wide range of chemical products and has in excess of 50,000 employees worldwide. Monsanto has had an active interest in the Toxic Substances Control Act from the time of the first congressional discussions up to and including the present. The company supported passage of TSCA and continues to support the underlying principles, policy, and approach to the law. We have seen significant progress toward achieving the congressional intent of TSCA, and see no reason for legislative change.

The Environmental Protection Agency is charged with the implementation and enforcement of TSCA and has broad authority to do so. While we don't always agree with the EPA rulemaking activities, we do believe that TSCA framework coupled with the rulemaking process of proposal and comment has resulted in reasonably balanced implementation.

Monsanto experience with TSCA has taken several forms. No. 1, TSCA has served as an audit function for our internal product safety programs. No. 2, the law has provided increased sensitivity and a degree of uniformity across the chemical industry on health and environmental issues, and has served as a safety net to prevent unreasonable risk.

Three, TSCA, in concert with other health and environmental laws, has brought an increased awareness to our management regarding toxic substances issues. Four, TSCA has increased the cost of our doing business. These costs take several forms, some of which we feel are justified; others we seriously question.

I would like to expand on the first two points. Monsanto has an active program of assessing new and existing chemicals. This activity has been in place for a number of years, and is part of our product safety program. We assess new chemicals and test them as necessary before commercialization. We monitor, test, and assess our existing family of chemicals on a continuing basis, and take action as appropriate on these. Product safety is part of our social responsibility commitment, and it is just good business from both a customer relations point of view and a legal liability perspective.

EPA programs under TSCA have provided an external review or audit of our product safety activities. For example, before a new chemical can be manufactured we must submit a premanufacturing notice to EPA. This notice and review by EPA provides a crosscheck on our internal review process. To date, we have submitted in excess of 25 PMN's. We provide in the notice information as required by the act, plus data and information developed during our internal review. The optional information varies considerably, depending on the material type, the use planned, or the substance.

Testing information provided with the PMN also varies. For some materials testing is necessary to clarify potential concerns. For these materials the test programs are tailored to the specific chemical and to the anticipated exposure. If, for example, the substance will find its way into the aquatic environment in significant amounts, we feel it is important to know if it biodegrades and how fast. For other materials such is not the case, and little if any testing is needed. For these materials, such as structural polymers similar to our existing product lines, our scientific review panel are of the opinion they can reliably assess the hazards based on their knowledge and experience.

For almost all of our PMN submissions, we have been contacted by EPA asking clarifying questions. In a couple of cases we have been challenged and have been required to provide additional information to support our position. In our experience EPA is providing a thorough and professional review of PMN's.

I would like to challenge a statement made by Ms. Hall regarding the superiority of the European system. It is clear that the U.S. system is in the lead on the toxic substances issues, and has reviewed and processed over 2,500 PMN notices. The Europeans have essentially no experience with this process.

Turning now to existing chemicals, in 1982 we spent in excess of $10 million testing the health and environmental effects of our products and raw materials. We also support the Chemical Industry Institute of Toxicology and actively monitor Federal testing programs and the scientific literature. These programs are designed to provide the scientific base necessary to insure that our products and workplace materials do not pose unreasonable risk.

The Interagency Testing Committee and EPA provide an external audit of our programs. Both the ITC and EPA prioritize chemicals that have data gaps and identify specific testing needs. This process got off to a rocky start but has improved significantly. ITC's screening procedures are now recognized as state-of-the-art, and current information-gathering procedures have qreatly improved ITC's data base.

Monsanto has provided input to both groups to assist in their decisionmaking. For example, approximately 30 reports dealing with exposure of Monsanto products have recently been provided to EPA for assessment purposes. We have submitted copies of over 550 health and safety studies for EPA review. This group of studies translates to a stack of studies 10 feet tall.

Over the last 2 years we have voluntarily submitted information on over 30 materials under evaluation by ITC. We are involved in negotiated testing agreements on half a dozen chemicals and chemical families, several of which have reached closure and test data is in EPA's hands.

Ms. Warren expressed concern with this program. The policy of TSCA is that adequate data should be developed. The facts are that this is happening. It is coming in quicker and with less expenditure of EPA resources and industry resources. If a rule is not needed, why put a rule in place?

Each of the above-mentioned statistics represents an external input or audit of Monsanto's testing and assessment program. Monsanto is not alone in its generally independent approach to TSCA. However, TSCA has served to bring the chemical industry together to discuss toxic substances issues. Monsanto has been actively involved with several trade associations on TSCA issues, and I currently chair the Chemical Regulations Advisory Committee of the Chemical Manufacturers Association.

Industry discussions amongst ourselves and with those external to the association have been healthy. This activity has brought about an increased awareness on the part of those involved and an upgrading of product safety in general. On the other hand, TSCA, and EPA specifically, serve as a safety net for those less informed or just recalcitrant regarding appropriate product safety programs. Examples of the safety net in action include the PMN process, EPA's 8(e) substantial risk notification program, and their existing chemical program that is just now developing into full bloom.

In summary, I urge the committee on behalf of Monsanto to reauthorize TSCA in its present form. The flexibility provided by the law compliments industry product safety programs such as those in place at Monsanto. At the same time, TSCA provides the necessary safety net to insure that chemicals do not pose unreasonable risk to health or the environment. We believe that EPA has made great strides toward implementing and enforcing the act to insure compliance with congressional intent. Problems we have had to date with TSCA are best handled, we believe, through the normal regulatory process.

Thank you for this opportunity to present our views.

Senator DURENBERGER. Thank you very much.

Mr. Feldman?

STATEMENT OF JAY FELDMAN, NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. FELDMAN. Thank you, Mr. Chairman.

I am Jay Feldman. I am the national coordinator of the National Coalition Against the Misuse of Pesticides.

What I wanted to do to was try to take us out of Washington and share with you part of a piece of mail we recently received from a victim of chlordane contamination and poisoning. This woman from Arizona writes: "On a personal basis, the most concise way I can describe what has happened to my life is that while it didn't kill me, it makes me for the rest of my days wish it had."

She says it is a fascinating thing and it is a cruel story. While this may be a dramatic representation of an individual's problem, it is a real representation. From our point of view it represents a regulatory and statutory system that isn't working to protect the public against toxic chemicals.

Sitting here today is very interesting for me because I spend a lot of time focused on another statute, called the Federal Insecticide, Fungicide, and Rodenticide Act. It is very clear in working with that act and in working with people that have problems, that chemicals don't respect political jurisdictions and for sure they don't respect the committee jurisdictions that have been defined by Congress. Therefore, I come to you today to ask you to consider using the authority vested in you to address gaps that exist in the regulatory and the statutory systems that have been set up by Congress to better protect the public from exposure to toxic pesticides.

You can capture or characterize the problems of pesticides in a number of ways. We have recently seen problems with faulty data, products being registered with faulty data, as mentioned earlier, produced by the Industrial Bio-Test Laboratories. We see products registered with no or inadequate tests, including tests for cancer, for birth defects, for genetic damage. We see virtually no public information on product risk. We see back-door registrations and continual and expanded marketing of products that have been poorly tested or registered with no data. We see nonenforcement of the Federal pesticide law, and we see the unconscionable exporting of banned and unregistered pesticides which ironically enough find their way back to the United States on imported foods.

Now I have also heard something today that I hear very often in other committees of Congress, particularly this year, and that is many representatives of the industry asking for no change. From the experience I have had, I see communities that no longer have safe drinking water becoming increasing impatient with congressional inaction in this particular area. I see people whose towns are sprayed with herbicides that were once used in Vietnam also becoming increasingly impatient and asking for change.

People that consume beef and fish that show surprisingly high levels of dioxin would like to see some congressional action, and homeowners across this land who, given the construction of their homes, have been inadvertently poisoned by chemicals such as the chlordane example I raised earlier. We have a situation, also, in which neither the newborn nor unborn children who aren't here to speak for themselves, I am sure you would agree, don't look forward to a life jeopardized by exposure.

Therefore, I guess what I am asking you and other members of your committee, Mr. Chairman, is to look at the basic question that we look at, and that is whether workers and the public today are receiving adequate protection from potentially life-threatening toxic chemicals and toxic pesticides. We do not think so, as I think I have made pretty clear, and what I wanted to do with the rest of my time here is to show you the gaps that you could address and this subcommittee could address under its authority, I believe.

There is the question of the lack of or missing health and safety data on pesticide products that are registered by the U.S. Environmental Protection Agency. It turns out that between 79 and 84 percent of the pesticide products on the market today have not been adequately tested for cancer. Between 90 and 93 percent of the products have not been adequately tested for genetic damage, and between 60 and 70 percent have not been adequately tested for their ability to cause birth defects.

We have the situation which I am sure you have heard a lot about, and that is faulty data, in which pesticides have been brought on the market with testing that has been found to be faulty. However, investigative reports indicate that the problem is much more widespread than one particular lab, the Industrial Bio-Test Laboratories, Inc. In fact, Canada, faced with a similar situation to that in the United States, has banned six products.

EPA officials maintain that the existing Federal law prohibits them from taking action similar to Canada because, and I quote, "valid evidence of risk as opposed to lack of information" prohibits them from taking any action. As a result, products remain on the market with invalid tests supporting their registrations.

You heard last week from Don Clay, Acting Administrator for the Pesticide and Toxic Substances Division of EPA, and he talked to you about a lab audit program. The lab audit program, he failed to mention, is extremely ineffective. This is another gap that needs to be addressed immediately. Although EPA has a lab audit program that has been operating since 1977 and has tested nearly 100 laboratories, questionable lab practices continue.

According to a recent report, and I quote, "None of the most suspect labs have been audited for a second time, and despite the questionable value of many of the studies, not one pesticide registration has been withdrawn." In a staff report recently produced by a subcommittee on the House side, Department Operations, Research, and Foreign Agriculture, it was found that there is no solid indication that any decisive regulatory or enforcement actions have been taken.

Well, there are a number of other points which I would like to raise which there aren't time for. There are no standards and, according to Federal officials, no authority to establish indoor residue standards for pesticides that are found inside people's homes. Pesticides remain on the market under State standards which after less protection than Federal law. There is no longer efficacy data required, generally, across the board, for products that are being marketed.

In conclusion I would like to say, in a short conclusion, that it is turning out, Mr. Chairman, that EPA doesn't even believe that we are able to clean up after a lot of toxic pesticide problems that we as a nation are identifying. EPA's toxaphene decision is a recent case in point. Therefore, I urge you and the committee to take a preventive approach, to look at some of these problems in a preventive way, so that we don't have to face a moral and social dilemma of what to do with a pesticide that should be taken off the market.

Senator **Durenberger**. Thank you very much.

I am going to have the staff pass out these things I talked about earlier, which is five recommendations that came out last week, and ask you—probably starting in the order you testified—to react to them.

However, while they are doing that, and to give Dr. Smith time to look them over, since he will be the first one, I would like to make an observation to put all of this in context for those of you who weren't here to hear the opening statement that I made with regard to this whole matter.

I cannot recall a situation recently that I have been involved in, in which I felt more like Solomon after an hour and a half of testimony. Clearly, half of the witnesses believe that this is their baby and we shouldn't touch it, and the other half think that it is someone else's. This makes it very, very difficult.

Dr. Koplin pointed out to us, sort of reaffirming other things that we have heard, that TSCA was what other people have called a gap filler. It was a part of a total approach to how we deal with environmental contaminants. It just took longer to pass than a lot of others, but its importance was that it was intended to provide us with a knowledge base, a data base that we needed in order to deal with contamination in soil and air and ground water and other forms of water, and in the workplace and with regard to consumers and so forth. A lot of people have called it a gap filler, and Mr. Feldman has just said that the gap is still there and that we ought to some way take advantage of the underlying statute that we are talking about to continue to fill that gap.

Well, this subcommittee has both a narrow and a broad purview. It is narrow in that it is entitled "Toxic Substances Subcommittee," and it is broad in that it is called the "Environmental Oversight Subcommittee." When I inherited this subcommittee I made it my job not to try to be all things to all people. We thought the best thing to do is to walk before we run and, as I said to Clay, run before we get into a marathon and fall down and break our arms.

Therefore, this 3 days of hearings may be followed by more hearings, because I am not Solomon and I don't know any of my colleagues that are. We also got a start a month or so ago on looking at what we are doing in R&D, and it is only a start. We really have not tackled the whole issue of R&D. I have a strong suspicion that we are spending a lot of money on R&D but we are doing it in a wide, spread-out fashion all over Government and in the private sector, and there is little appropriate relativity to help us come to grips with the knowledge problem.

One of the areas that this subcommittee—because of its chairman's interest and because of the gap that exists—is particularly interested in, of course, is ground water. At some point this fall, I suspect, after we have finished off the R&D hearings, extended these hearings if that is necessary, and done some more work on ground water, we will be back to deal specifically with the relativity between TSCA and other toxic substances legislation and some of these other issues that I have just expressed a concern for.

That is to put in perspective for all of you the value of your testimony to the subcommittee, even though there may seem to be disagreement, if not in substance, in objective. You have each made a substantial contribution to our understanding of the problem and the opportunities.

Therefore, if I may start with Dr. Smith, I will caution all of you to try to be as brief as possible, and to perhaps take these and expand on them in greater detail in written response if you would like to do that. Perhaps after this hearing, to avoid all of us having to come back together periodically over hearings, we may propound other questions to all of you who have appeared as witnesses. However, we felt these five would be an important way to sort of tie together, on the basis of what we have heard in the past, some of the specific recommendations that each of you as experts might have.

If we can start with Dr. Smith, for those in the back of the room who do not have the benefit of the questions, the first relates to premanufacture notification requirements, whether we should require identification of high-risk categories of chemicals and uses for these, placing the burden on industry to resolve the risk question by testing or exposure controls, and exempt low-risk categories—as defined by SAR, for example—by law.

The second is followup testing: Establish rebuttable presumption for testing at specified post-market production levels and/or elapsed time. That is the pay as you go testing that we talked about last week.

The third is existing chemical priority testing: Provide more production or use data to the ITC to improve the recommendations; require testing by administrative order rather than by rule. This is a recommendation we got from a couple of people.

Fourth, with regard to confidential business information, require that CBI claims be justified and allow State programs access to CBI data when necessary to protect their citizens and the environment, possibly on condition that the State have a program for CBI protection.

Fifth, is testing of chemicals. The Federal Government now spends over $30 million per year to test market chemicals for chronic and acute health effects. We might amend applicable laws to transfer this cost to industry through a uniform permit fee, with a provision allowing exemption for small businesses.

Now those are some of the recommendations that we have been given by others, and we will ask Dr. Smith to comment on them first.

Dr. SMITH. Thank you, Mr. Chairman.

As far as response to the first question, I think that industry does have the burden and has taken up the burden of testing those chemicals that are high-risk. I think it is very definitely to the advantage of TSCA that we set exemptions for low-risk chemicals. I think it remains, again, on a case-by-case basis as to what testing is required for each particular chemical, so I would not recommend that we set a high-risk category.

As far as following up testing goes, the rebuttable presumption type of approach has some difficulties with it in that, one, with rebuttable presumptions we can only list questions where we have had problems before. The things that have given us the most problems were new things that we did not anticipate, and these are best addressed by the experts as one looks at the particular chemical.

As far as the "pay as you go" approach, I think this is the type of approach that we are talking about. As a new chemical expands in its use and exposure, more data is required to evaluate that.

Existing chemical priority testing, I think that there is and has been a tremendous improvement in the communication between ITC, and industry, providing more data and more information for appropriate recommendations. I think the opportunity for providing additional data after ITC makes its recommendations should remain open, to get as much data as possible.

Requiring testing by order rather than rule, I think this has many, many pitfalls in that it depends entirely too much upon who happens to be in office giving the orders rather than a society where we have checks and balances.

Confidentiality as far as business information goes, I think industry agrees that toxicological information should be shared and the public should have access to it, which they do now. I think that there is a lack of appreciation of the potential value of exposure information from a competitive point of view, both among industries within the States and with industries from outside of the United States. This data is provided to the Agency so that they can make their judgments.

As far as testing of the chemicals, I think there has been an undue overlap of testing by Government and industry. I think that the proper role of the Government as far as testing is to help push back the frontiers of science by research-type testing, and to look at those chemicals which have a high need, but are of low economic value to industry, where an individual company may decide to terminate production of a chemical with low volume and low sales rather than test. I think it would be appropriate for Government to test these chemicals.

Other than that, I think that the voluntary testing that we are seeing with the section 4, in communications between the national toxicology program and industry that is taking place now, and the oversight that is going on now, is most helpful. I think it would be a mistake to suggest that the Government do all of the testing with some type of permit fee or some way of taxing for the Government to conduct these tests. The expertise lies within the chemical industry and you get much better testing when directed by the chemical toxicologists.

Senator DURENBERGER. Thank you very much. It looks like 30 minutes, if we can do it in that, we can get out of here in time for lunch.

Ms. Warren?

Ms. WARREN. I guess I would need to think about this requiring identification of high-risk categories because it sounds in theory like it would possibly be workable, but I just can envision years of squabbling over what is a high-risk category and going through these lengthy rulemakings to try to come up with something, with the same kinds of arguments being brought out that you have been hearing here today.

It seems to me that it would be easier to just give EPA the authority to define what sorts of general information they need to evaluate new chemicals. They may say, in defining what kinds of chemicals ought to be exempted and by definition the ones that aren't exempted, that they need certain types of information.

However, it seems backward to me to try to figure out all the kinds of risks that could exist, list them, and then start requiring the industry to resolve the risk questions on those. It seems to me that that is better, what you have proposed is better than what we have now, but I am not sure that that is a better idea than having some prescription of minimum testing that most new chemicals should have to go through, unless there were good reasons why they shouldn't.

As far as exempting the low-risk ones by structure activity, I have real problems with that because, as one of the other witnesses said, the mere change of position of a few molecules here and there can tremendously affect toxicity. I don't think that Congress—with all due respect—I don't think Congress is really in a position to make those kinds of scientific judgments and put them into the law.

I would be equally uncomfortable seeing safety standards for airliners or something like that legislated by Congress. I think that some determinations should be left to the entities that were created by Congress to develop the expertise and have it. I think that an agency like EPA could attempt to define, as they have, what are presumably low-risk situations. However, a legislative definition based on structure activity makes me very nervous.

Just to give you one example that you can think about, the difference between methyl——

Senator **Durenberger**. If you do, you are not going to have much time for the next four items.

Ms. **Warren** [continuing]. The structural difference between methyl and ethyl alcohol is very slight. Yet, one of them is poisonous, and one of them you have in a cocktail. I think it would be difficult to express these distinctions in the law.

For followup testing, the European system has a 1,000-kilogram cutoff. When the volume rises to 10,000, certain kinds of testing must be done. I don't have a problem with doing that. I just would like to see some testing of new chemicals. I am not advocating a wholesale adoption of the European system. I do think that they are doing something more than we are and finding out more than we are about new chemicals. Their system is designed to find out more, anyway.

For the existing chemical priority, I don't quite understand the advantage of an administrative order. Is it faster than a rule? EPA has put together a rulemaking system that is so complicated, has so many tiers of agency review, and takes so long, that they cannot use it. The statute said, "* * * the Administrator shall, by rule * * *," and the EPA by administrative order and the administration through the Executive order that requires cost-benefit assessment, have made rulemaking so cumbersome that it cannot be used. Maybe an administrative order would help that. That doesn't go to the problems that I raised about notice to foreign governments that a product is under test by a section 4 rule or all of the other provisions that refer to rules, though that could be easily remedied if you changed the word to "order." I am also concerned about what the public's role would be with such a change.

For confidential business information, I think claims should be justified. However, the point that I was making is that the definition is too broad. There is a recent decision in the U.S. Court of Appeals for the D.C. Circuit, looking at health and safety studies and information related to health and safety, that defines "trade secret" as a commercially valuable formula, plan, or process. It gives confidentiality a specific definition that really relates to trade secrecy, instead of the sort of ambiguous definition in current law which allows people to claim confidential anything they want to, including things that are unquestionably health and safety information.

Finally with respect to testing chemicals, I think one purpose of TSCA as stated in section 2, is that the people who make a chemical should develop the data. I think there is an inherent conflict of interest there that we have seen repeatedly: People who want to market something have a vested interest in designing the tests and having the results come out in the most favorable way.

The reason for providing that testing shall be required by rule was an attempt, in the context of the IBT scandal back in 1976, to minimize such problems by having the agency oversee the testing, specify the protocols, and make them enforceable, et cetera. I think that those who profit from a chemical should be financing the cost of the testing; I am not sure they ought to be doing the testing. I would support amending the applicable laws to make the people who produce the chemicals and profit by them pay for that, but I don't know whether that would result in more testing or not. All it would be is a way of bringing more money into the Federal Treasury to help pay for it.

Senator **Durenberger**. OK. Thank you very much.

Dr. Scott?

Dr. **Scott**. I agree that trying to define a high-risk category would probably not be a worthwhile exercise. It seems that this would just be another case of saying, "For this type of high-risk category, let's generate this information," which is somewhat circular. For risky chemicals, generating a predetermined number of type of data somehow begs the question. It seems to me that under the current authority that EPA has, under some of the studies that have taken place, that for chemicals that have a defined exposure and somehow looking at the hazard that more information is provided. I think the OTA study showed that for consumer chemicals more data was provided.

For followup testing, I think again that EPA does have the authority to require some sort of a trigger at a higher production volume. Again, they have the "significant new use" rules where they can open up a negotiation process again.

I agree it would be a good idea to provide ITC with more information further upstream than is currently being done. Regarding confidential information, I would be very much opposed to a requirement that claims for confidentiality be narrowed even further yet and that claims be justified, or some requirements put in there that confidential information be justified to remain as confidential.

On the last point, as to testing chemicals, I think I will pass on it to some of the more experienced industry spokespersons.

Senator **Durenberger**. Thank you very much.

Ms. Hall?

Ms. **Hall**. Yes; with regard to No. 1, premanufacturing notification, I agree with what Ms. Warren has said and the previous speaker has said about the difficulties of identifying a high-risk category. For instance, identifying it on a basis of whether it is a polymer or not we don't think is a useful way of categorizing chemicals. Similarly, we would strongly object to exempting of low-risk chemicals as defined by SAR because we just don't think SAR is sophisticated enough to even get to that point.

Senator **Durenberger**. Is there an alternative, or do you just object to the concept of distinguishing between high risk and low risk?

Ms. **Hall**. Well, if you require testing there will probably have to be some flexibility. How you go about definiing that flexibility to exempt categories is something that is really a very touchy subject. SAR, we believe strongly, is not a way of doing it. If you do it on the basis of size of enterprise, you run into trouble with cases, for instances, like Life Sciences and kepone. Life Sciences was a very small enterprise that caused a whole lot of damage, and it was also a site-limited application which caused a lot of damage.

Likewise, if you do it on the basis of poundage you always have to remember that dioxin is produced in this country somewhere between 50 and 100 pounds per year right now, and that is very, very small. It is something that just has to be very carefully thought out. I don't think we have any answers right now.

Followup testing seems like a fair recommendation.

With regard to existing chemical priority testing, I guess we would add to that that there should be more disposal information given as well. I have some questions about when you move from a rule to an administrative order, what kind of public participation would be involved. Would other outside interests besides the people who are subject completely to the rule be involved? An administrative order takes on the essence, to a certain degree, of an enforcement proceeding. Typically third parties are not involved in that, so some sort of hybrid administrative order where the public has a role may be appropriate. I agree that would be easier to get out than a rule, and that is appropriate.

Confidential business information, I also would like to see this changed a bit. As Ms. Warren has indicated, the presumption should be that it is not confidential unless the company can establish that it is truly a trade secret, and that is a little broader than what you have here.

I think that No. 5 is appropriate, testing chemicals and allowing the costs to be transferred to industry. That is consistent with the goal of TSCA that costs be borne by industry.

Senator DURENBERGER. Thank you.

Dr. Grunseth?

Dr. GRUNSETH. Mr. Chairman, we have been busy collaborating here and I have asked that Chuck Lentz comment on these questions. As an industry, we find some of them interesting but we would like to have a little more time to view them amongst ourselves.

Senator DURENBERGER. Mr. Lentz?

Mr. LENTZ. As far as developing categories of chemicals for the purposes stated here, I think that we have had considerable difficulty in attempting to do that. In our own experience with CSMA's our Scientific Affairs Committee, where we have had discussions with EPA and it is an extremely difficult thing to do. I am much more comfortable myself leaving that up to the professional toxicologists and interacting with EPA on an individual chemical basis. However, we will study that further and would like to come back with a better answer.

Senator DURENBERGER. Well, you will have plenty of time.

Mr. LENTZ. The followup testing, I think that as a philosophy that is correct, pay as you go, and our experience is that we do that. We also believe that there is plenty of authority for that to take place today within TSCA. Some earlier experience with rebuttable presumption activities, if you will, is that that tends to establish a list of chemicals which immediately becomes suspect in itself, and it does cause problems in the business world.

Our experience with the Interagency Testing Committee and with the kind of information that they ask is that they have asked for lots of information, and specifically as mentioned here, production and use data. We have always supplied that. They have never come back to us and said, "That is inadequate. We need more." Therefore, I am assuming that what they are getting is adequate.

It is our firm position that immediate justification of confidential business information claims is unwarranted and a waste of resources since most confidential information submitted to the Agency is never requested. Whenever we are informed of a request, industry promptly responds with the substantiation needed for the Agency to make its decision as to whether the information is entitled to confidential treatment.

I feel that there is some confidential business information that is quite standard and we shouldn't have to justify exactly the same thing each time. I think the question itself would have to be maybe a little bit more specific on what those items are, but I know in our own experience that it seems unnecessary to, say, use the same language each time to justify certain types of confidential business information. For example, any manufacturing or processing type of data is quite cherished in the chemical industry. It is one of the things that is unique to each of us, and we should not be required to share that with the competition.

Senator DURENBERGER. Are you willing to tackle the second part of that one, which would allow State programs access to confidential business information data if they have——

Mr. LENTZ. I'm sorry. Where are you?

Senator DURENBERGER. I am still on No. 4. No one has really addressed the second part of that.

Mr. LENTZ. We have done that in our own State of Michigan, shared this type of information. What we usually ask for is assurance that they have a system where that data can be protected, that confidential business information can be protected.

In fact, Dow Corning and many other CSMA members share confidential business with agencies in various States but only to the extent they need the information to perform their tasks. Often we have candid and cooperative discussions on this matter. Typically, the agencies recognize that if they receive confidential business information which they do not need, it only increases their administrative burden as specific precautions must be taken to protect such information.

There is however, one continuing source of trouble in allowing States confidential business information—access to this data by various State freedom of information acts. As you would expect, there is no uniform degree of protection from State to State, and in some instances, there may be little or no protection at all. For example, the Michigan FOIA section 13(g) exempts from disclosure trade secrets as long as they are voluntarily submitted and not a condition of receiving a license contract or other benefit. I believe you can see from this example how varying State standards could create serious problems for CSMA members.

If this subcommittee were to recommend that States take a more active role in the administration of TSCA, I would suggest that there also must be a national standard for protecting confidential business information. This standard should be based on the traditional common law definition of trade secrets.

As far as testing of chemicals, our own experience is that we used to have our testing done in contract laboratories. A few years ago we decided that we would do our own testing, and I think we are very pleased with the results of that. We feel we learn much more from doing our own testing and having our own in-house experts than we do when somebody else does the testing and just tells us what those results are. I would not favor anything that would tend to make it necessary for somebody else to do our testing of our chemicals.

Senator DURENBERGER. Let me call your attention and that of the subsequent witnesses to a couple of words that are in there, and they are in there because of what we got out of GAO or OTA or somebody. Yes, there is a lot of testing going on, and yes, there is a lot of information, but when it comes to some of the chronic and acute health problems—we talked about mutation problems and so forth—it looked like we were getting very little test data coming back in that area. Therefore, I am sort of distinguishing the testing for chronic and acute health effects from some other.

Mr. LENTZ. Under TSCA I think what is evolving is a lot more of the long-term, chronic testing that is on a cooperative basis with expenses being shared by companies under the umbrella of TSCA. That is taking place.

Senator DURENBERGER. OK.

Dr. Koplin?

Dr. KOPLIN. On No. 1, I think we know enough about high-risk categories of chemicals to make this a continuing, useful activity. Part of my concern is that we have known so much about high-risk chemicals and done so little about them that we should not in any way weaken our approach to the high-risk question.

For example, I was doing a little research before I came, and we first knew about the lethal effect of asbestos—it was first reported—in 1899. In 1935 it was related to cancer, and look how long it has taken us to decide that asbestos is a high-risk substance, and just only this year have some sort of rule promulgated with respect to exposure of children in schools.

Therefore, my feeling is that we can identify categories of high-risk substances and should continue to do that. Now, if something brand new is produced that does not have a categorical relationship to anything else, I think then we are talking about some kind of research that is necessary, and I will comment about that in connection with No. 5.

No. 2 I am going to pass on, because I don't think I quite fully realize the relationship between pay-as-you-go and rebuttable presumption.

The question of whether you use an administrative order or a rule with respect to chemical priority testing, has some implications for political change, as has been mentioned by the first speaker. I think perhaps that is what the Senate oversight committee is all about, to be sure that the law is administered correctly in one way or the other.

However, I don't think it makes a great deal of difference as far as that is concerned. In other words, I think maybe there is a safety factor. If there is going to be a change of administrations and different ways of administering this section of the law, perhaps a rule is better. At least it provides a little more public involvement and oversight, so I would lean to the side of following the rule rather than the administrative order there, especially under present conditions.

Confidential business information, we have some experience with that in New Jersey. We are trying to finalize a "right to know" law under which manufacturers in our State will be allowed to avoid labeling the substances in their plants which involve business secrets, manufacturing secrets. I think that can be handled quite well by codes and by numerical designations and other methods. If I understand this question correctly, I think that States can do this or the Federal Government can do this and I think there is a way around this.

Now as far as testing chemicals is concerned, I don't know how all these tests are done, to tell you the truth, especially with brand new substances. I think it should be in the public area and it should be financed in part by the industry, as has been suggested.

For example, one thing that occurs to me, as I mentioned earlier, from a public health perspective it seems at some point there needs to be some information about the effects of these chemcials on humans. I don't know how that is done. It is done with animals. I think that this is an area for research and that should be financed through the Federal Government.

I think that we need more of that. We need to know at least, if we have some judgment calls, we have some knowledge that something might be dangerous but perhaps should nevertheless be used, there needs to be some protection for the people that are inadvertenly exposed to it, perhaps some quid pro quo compensation system or if the substance is released—maybe this is too far out—perhaps it should be traced as it is used in society and some record kept of how it affects the individual. Therefore, I am saying that I think we need to do a whole lot of work on how we study human health effects as part of testing.

Senator DURENBERGER. OK.

Mr. Condray?

Mr. CONDRAY. Yes. On the first point, dealing with the high-risk categories, TSCA currently addresses in section 5, the risk list, which I think speaks pretty much to this particular situation. The agency, EPA, has authority to use the risk list. I think EPA is giving under consideration at this time how to best to utilize the authority they have.

I think, like Mr. Lentz, we would like to see what their specific proposals look like. I think it would be difficult, as Ms. Warren points out, to define those categories in some cases. However, I think at this point in time we would be open to proposals, in that the act requires or stipulates the authority for EPA to use the risk list concept.

With regard to the low-risk situations, I think the answer to that is yes and no. In some cases we think that SAR can predictably define low-risk situations. I made reference in my testimony to structural polymers, which by SAR I think one could reasonably come to the conclusion that those were low-risk materials. Here again, the statute provides exemption capabilities, and I think the agency currently—well, I know the agency currently has programs underway looking at where they can utilize the exemption powers under the act to handle low-risk situations. In other cases clearly SAR is not appropriate for low-risk situations and we would not buy into that.

With regard to followup testing, we would be opposed to the rebuttable presumption approach but at the same time do believe that there are authorities under TSCA—namely the SNUR provisions and the section 8(a) provisions—where EPA can utilize their authority for followup action, and I think that they should. Where situations do look as though there may be risks associated with the material as it moves further down the commercial chain, the agency should recognize that in their PMN review and utilize their followup mechanisms just as we in industry do that same kind of followup as we move down the commercialization road, of a new product.

With reguard to the existing chemical priority system, I think the ITC does and should have information necessary to make decisions. As we know, the ITC has made available, through Federal Register notices, their candidate lists of materials that they are currently giving consideration to, they have openly sought assistance and input reguarding these materials.

From an industry perspective and from a Monsanto perspective, it is just good business to provide the ITC with information. It is very appropriate that ITC have information early on to avoid unnecessarily moving further down the regulatory process. It is in our interest, if you will, to have ITC well-informed. Therefore, I think that process is working under the voluntary mode very effectively.

With regard to testing by administrative order, I think that it would run into real problems because testing is very much a scientific issue and I think we need the scientists involved. Those in the EPA and industry and in the public sector, I think, need to be involved in determining what kind of testing rules are appropriate. We have section 4 to deal with this need.

With regard to CBI, it is very burdensome every time information is submitted to EPA to have to justify the CBI claims at that point in time. It seems to me more appropriate—since we have the Freedom of Information Act—if the public is concerned about a particular piece of CBI they can file through FOI for that information, and there are procedures in place with the EPA to then go back and determine, "Does that material truly justify the CBI claims made by the people submitting the information?"

Senator **Durenberger**. Does all that have to be done on a case-by-case basis, or have we learned enough from the Freedom of Information Act filings to date that might tell us some way to amend the CBI?

Mr. **Condray**. Well, I think EPA experience would indicate that there have been few, if any, requests by the public sector regarding CBI. Therefore, I think the question is, why do all the upfront work if the public isn't really trying to gather this information.

Therefore, it seems to me to be more the other way around. If the public has a concern about a specific substance, then they should make the request and that is the time, the submitter should be faced with the burden of justifying whether his or her claim is appropriate. I think the provisions are in place to deal with that, and I think the FOI Act is the appropriate channel.

Senator **Durenberger**. I can understand that of the organized public, a couple of whom are here, who might decide to do that. However, they aren't going to do that on every claim and they aren't going to do that on every filing.

Ms. **Warren**. We filed FOI requests on that information early on, but the EPA's process is very lengthy and requires going to court in the end, every time. Not only that, but the time periods allowed for review inside the agency were longer than the PMN period actually even was, that is, more than 90 days because EPA has repeated 30-day periods for making the confidentiality designation, and considering the appeal if we were denied our request. It is impossible to work through it that way, and that is the reason that no subsequent requests have been forthcoming from us.

Senator DURENBERGER. Not starting a debate here, but in your opinion is there anything to be learned from FOIA filings that would help us just amend that provision of the act that relates to CBI?

Ms. WARREN. It would be helpful either to expedite the review period inside the agency—if you are going to rely on FOIA as the first time anybody challenges a confidentiality claim—or let EPA, if everybody knows that this kind of a claim is going to be made, put a numbering system on and let manufacturers check off, "This is based on number 1, this is based on number 4, this is based on number 3," as a substantiation of claims and leave it at that instead of letting all the substantiation happen later on and require us to go to court if we ultimately want to get the information.

Senator DURENBERGER. OK.

Mr. Condray?

Mr. CONDRAY. Can I respond to that?

Senator DURENBERGER. Well, yes, you may finish your testimony and respond to that in connection with it.

Ms. WARREN. I'm sorry.

Mr. CONDRAY. I forget the exact date, but the first year or so of the EPA PMN process we were required, as industry, to substantiate confidentiality claims. EPA kept records as to how many of the public came in and requested that information, and it was very, very low. It was just a pittance of the PMN's that had been submitted that had had any claim to look at that information, so it was really the agency's decision that this was an undue burden on industry to require all the upfront substantiation when in fact that information was going into a dead file.

Senator DURENBERGER. That was in the first year of the act.

Mr. CONDRAY. It was the first year, so I don't know the exact timeframe, but the agency then later came out with a revision to their internal process, saying, "We don't see justification for the up-front substantiation," with the exception of chemical identity, which still does require substantiation.

Let me go on. With regard to making information available to the States, we strongly support that and in fact some States have had programs underway to develop their own inventories of chemical substances. We have said to them, "Use the inventory that is in place with EPA. That is the appropriate way to go." It is a waste of resources to go back and reinvent the wheel, if you will, in the States. Therefore, we would strongly support making information available to the States, assuming that the States likewise had provisions to protect confidential information.

With regard to testing, I think it is very appropriate to say that there are places where the Federal Government should test. We think the Federal Government has an oversight responsibility. In my testimony I made reference to the audit function that the Government has, and I think that testing is one approach to that.

I would like to say that, dealing with chronic and acute health effects, I made reference to the fact that Monsanto had submitted 550 health and safety studies to the agency. By far the largest bulk of those have been acute and chronic studies, so I am a little confused about the question regarding not having acute and chronic studies.

Last, with regard to the permit fee system, I think that this would create real problems. I think if there is need for industry testing, the provisions are there through section 4 to require testing, and the responsibility for those costs is likewise spelled out very clearly in the act, as to who should pay what.

Senator **Durenberger**. All right.

Mr. Feldman?

Mr. **Feldman**. I think the only thing I have to add to No. 1, in terms of what other environmental witnesses have said, is that we don't see enough attention being given to the identification of vulnerable populations or high-risk populations. You may in fact have something categorized as a low-risk chemical, but given its chemical use pattern, it may have deleterious effects on pregnant women or on children. This is an oversight, especially when you are talking about residues on food or ground water contamination or things like that.

In terms of No. 2, the problems we have seen with rebuttable presumption in other areas is that rigorous time lines are ignored and the reviews drag out. It is a process that cuts the time in which the public becomes aware of what in fact is going on, so as a rebuttable presumption is carried out and 5 years go by—as it did with toxaphene—the public and the user of a particular chemical are unaware that that discussion is going on, that there may be risk criteria that have been exceeded. Therefore, there needs to be some kind of notification, public notification, with this process.

In terms of No. 3, we don't want to see anything happen that would not allow for public oversight, essentially. What we have seen at EPA in terms of private decision conferences is industry sitting down with EPA and discussing future or potential regulatory action. This is not a process that we feel comfortable with. Therefore, anything that would preclude public oversight and involvement in the process we could not support.

In terms of No. 4—and this is a very big one for those working in the pesticide area—our basic position is that the public is not now adequately warned of potential risk. One of the reasons for this is that the chemical industry claims too often, we feel, that data should be in a trade secret category when in fact we believe it should be in the public domain.

We feel, for instance, that the industry should have trade secret protection for quality control and manufacturing processes, but when it comes to the health and environmental effects and safety data—and, I might mention, any information on inert ingredients in products—the public has a right to know what the underlying data is supporting that particular product. More importantly, the scientific community, the independent scientific community, should be free to engage in independent peer review so that both the agency and officials in the agency can be assisted in reaching their regulatory determinations, and so that the scientific community can play an appropriate oversight role.

In terms of testing, we would encourage some kind of shared data costs in terms of a financing system, and also emphasize here that the independent third-party testing function is extremely important. There is a kind of built-in conflict of interest when any legislation proposes that the regulated provide data on its product to the regulatory agency. Therefore, a third-party intervenor, if you will, is essential in creating some neutral appraisal of the data.

Senator **Durenberger**. OK. Thank you very much. I have a series of other questions that I am going to propound to individual witnesses and ask you to respond to them in writing because the hour is late.

Several of you claimed the small business exemption, and I am really going to ask you to lay out some detail on that because it seems to me 10,000 kilograms is about 10 or 11 tons a year. I am just as afraid of your 11 tons as I am of Monsanto or Rohn and Haas' thousands of tons. Therefore, I would like to put you to the written test of demonstrating why it is, or what form of a so-called small business exemption might be appropriate, because on its face with a little background in this area, it doesn't come home clear to me how it is that we are making substantial and expensive requirements on you that just plain ordinary good business people wouldn't be undertaking. Therefore, I will leave it to you in that regard, at least two of you who laid claim to that one, to substantiate that. Then to other individual witnesses, I will ask you individual questions that relate to your testimony.

Thank you all very much for the time you have given us. The hearing is adjourned.

[Whereupon, at 12:18 p.m., the subcommittee recessed, to reconvene at the call of the Chair.]

[Statements submitted for the record follow:]

CMA
CHEMICAL MANUFACTURERS ASSOCIATION

Statement of the

CHEMICAL MANUFACTURERS ASSOCIATION

before the

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON TOXIC SUBSTANCES AND
ENVIRONMENTAL OVERSIGHT

UNITED STATES SENATE

Hearing on TSCA Oversight

August 1, 1983

2501 M Street, NW • Washington, DC 20037 • Telephone 202/887-1100 • Telex 89517 (CMA WSH)

INTRODUCTION

The Chemical Manufacturers Association (CMA) appreciates the opportunity to present its views on the Toxic Substances Control Act (TSCA). CMA is a nonprofit trade association whose company members represent more than 90 percent of the productive capacity of basic industrial chemicals within this country. The chemicals produced by CMA's members are essential to nearly every sector of the economy. In 1982, United States chemical exports contributed a positive trade balance of $10.3 billion.

TSCA was enacted in 1976 and became effective on January 1, 1977. It is a complex and detailed statute. TSCA empowers the Environmental Protection Agency (EPA) to evaluate and, if necessary, regulate the effects of chemical substances and mixtures on human health and the environment. Within EPA, TSCA has been implemented by the Office of Pesticides and Toxic Substances (OPTS), directed by an EPA Assistant Administrator.

TSCA's coverage is comprehensive. It potentially applies to all chemicals manufactured, processed, distributed or used in the United States except where these chemicals are already regulated under certain other federal laws. TSCA thus affects not only the chemical industry itself, but the many industries that use its products.

The legislative debate that preceded the enactment of TSCA was protracted. Bills to regulate toxic substances were passed by both Houses of Congress in 1972 and 1973 but did not become law. In the enacted version, Congress sought to craft a legislative approach that would afford adequate protection to human health and the environment while preserving an innovative and dynamic chemical industry.

These interrelated concerns are reflected in Section 2(b) of TSCA, which states the Congressional policy of the statute. This provision declares that the Act's objectives are (1) to encourage manufacturers and processors of chemical substances and mixtures to develop adequate data concerning the effects of chemicals on health and the environment, and (2) to authorize EPA to take regulatory action respecting those substances and mixtures which present an unreasonable risk of injury. The Congressional policy emphasizes that these goals are to be achieved without unduly impeding, or creating unnecessary economic barriers to, technological innovation. Moreover, Section 2(c) states that it is the intent of Congress that EPA act in a reasonable and prudent manner reflecting a careful consideration of the economic and social impact of any requirements that the Agency adopts under the Act.

CMA and its member companies have maintained an active interest in TSCA since Congress began considering toxic substances legislation in the early 1970s. CMA supported TSCA's enactment in 1976. It continues to support TSCA's underlying policies -- that adequate data should be available to assess the health and environmental effects of chemicals and that EPA should protect the public from those chemicals which present an unreasonable risk of injury. Since TSCA's enactment, CMA has participated constructively in the development and implementation of EPA's TSCA programs. CMA believes that, over the last several years, TSCA has demonstrated its effectiveness.

The legislative objectives of TSCA, and an assessment of the law's implementation, must be viewed in proper perspective. TSCA was enacted as one part of a more comprehensive matrix of health and environmental statutes. In certain respects, TSCA's provisions were designed to address specific regulatory needs perceived by the Congress. In other respects, TSCA's provisions provide back-up authority supplementing regulation under other laws. One of the basic provisions of TSCA is Section 5, which provides a mechanism for the review of all new chemical substances before they are manufactured commercially. A second important provision is Section 4, which provides EPA with authority to require testing to develop data on health and environmental effects of existing chemicals. Additional information-gathering authority is provided in Section 8. When EPA identifies an unreasonable risk presented by an existing chemical that cannot be addressed adequately under other health and environmental laws, Section 6 of TSCA provides EPA with regulatory authority to reduce or eliminate that risk.

Although these are the most basic provisions of the law, TSCA is an intricate statute with many interconnected provisions. As a result, its implementation has been a complex process. Although industry has not always agreed with the actions EPA has taken in implementing TSCA, the record shows that the Agency has developed a commendable level of competence in administering the statute. After six years, there is unmistakable evidence that the law is working and that the purposes of TSCA are being met. For example:

> -- An efficient and sound review program has been established for new chemicals under Section 5 of TSCA. Under this program, EPA has now evaluated about 2,500 new chemicals. On those occasions where new chemicals have raised sufficient health or environmental concern to warrant control, EPA has taken action to protect the public.
>
> -- Extensive testing of existing chemicals is underway. This testing derives not only from EPA's actions under Section 4 of TSCA but from independent testing programs sponsored by industry and government.
>
> -- Management of risks associated with existing chemicals is being achieved by industry-initiated practices, regulations imposed under numerous health and environmental statutes, and EPA's existing chemicals program under Section 6 of TSCA.

Few, if any, observers would maintain that implementation of TSCA has been perfect. On various occasions, for example, CMA has challenged EPA actions that it believed were scientifically unsound, legally questionable, or unduly burdensome. CMA will continue to support improved administration of the law, but it is clear that the basic framework of

TSCA is sound and its revision is unnecessary. Any attempt to alter the law could seriously distort the integrated approach that Congress sought to achieve when TSCA was enacted.

EPA's present TSCA programs are producing tangible and realistic progress in meeting the Act's objectives. While major strides have been made in the implementation of TSCA, more remains to be done. Administrative improvements that CMA currently considers necessary include exemptions from full premanufacture review for low-risk new chemicals; flexible testing guidelines; effective priority-setting for testing; more rigorous scientific support for regulatory decisions; greater selectivity in collecting information; less inhibition of research and development; and more realistic approaches to controlling unintentional contaminants.

I. NEW CHEMICAL REVIEW

In enacting TSCA, Congress recognized that the most desirable time to evaluate information on a chemical to assess whether it could present any unreasonable risk to health or the environment was before commercial production begins. At the same time, Congress was concerned to avoid imposing burdens on the production of new chemicals that would stifle innovation and would be unnecessary to protect the public against unreasonable risks. For these reasons, Congress adopted a chemical evaluation procedure and rejected proposals for comprehensive premarket testing of all new chemicals or for a registration scheme of the type employed for pesticides, which are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) rather than TSCA. As designed by Congress, TSCA provides for authority to gather basic information on each new chemical that is sufficient to permit an evaluation of the potential risks posed by that chemical.

To permit such review, Section 5 requires that a premanufacture notice (PMN) describing the chemical, its anticipated uses, all available health and safety data, and other information must be submitted to EPA at least 90 days before the start of production. Where a new chemical will have substantial exposure potential or may be harmful to health or the environment, Section 5(e) allows EPA to delay or prevent its manufacture or use pending the development of test data or other information. Section 5(f) authorizes EPA to restrict manufacture or use where a new chemical presents an unreasonable risk of injury.

Effectiveness of EPA's PMN Program. As the first step in developing its PMN program, EPA prepared an inventory of all existing chemical substances manufactured, imported or processed in the United States. This inventory, which was based on reports submitted by industry under Section 8(b), lists approximately 60,000 substances. The inventory enables EPA and industry to differentiate between existing and new chemicals and is essential for the functioning of EPA's PMN review program.

After publication of the inventory, PMN requirements took effect on July 1, 1979. Since that time, EPA has assembled a multi-disciplinary team of experts to evaluate new chemicals and has established detailed procedures for processing and reviewing PMNs. Experience has demonstrated that EPA's PMN reviewers fulfill their responsibilities with a commendable level of professionalism and competence. To date, over 2,500 new chemicals have completed or are in PMN review. The new chemicals proposed for manufacture under Section 5 have varied in uses, chemical structure, exposure potential, and biological and ecological properties.

EPA has found that most new chemicals raise minimal health or environmental concerns and can enter the marketplace without restriction. In a letter to then-Senator Muskie dated March 18, 1980, former EPA Administrator Douglas M. Costle stated that "none of the new substances that have completed our review process . . . will present an unreasonable risk of injury to health or the environment from their projected production and use patterns." More recently, Don R. Clay, as Director of EPA's Office of Toxic Substances, emphasized that "a large number of the new chemicals we see in the premanufacture review program have proved to be of low concern, either because of low exposure or low toxicity, and do not warrant extensive testing or review at that stage in their commercialization."[1] These observations are confirmed by EPA's estimate that approximately 50 percent of all PMNs have completed review within 15 days after their submission and all but a handful of the remaining PMNs have completed review within 45 days.

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[1] Don R. Clay, "The Premanufacture Review of New Chemicals Under the Toxic Substances Control Act," presented to the OECD Chemicals Forum on December 4, 1981, at page 17.

EPA has taken prompt action on those few occasions where a new chemical raises sufficient health or environmental concern to warrant control. As of June 30, 1983, EPA has issued 10 orders under Section 5(e) prohibiting production of or otherwise regulating 22 new chemical substances or categories. PMNs for several other new chemicals have been withdrawn in the face of likely EPA action. Moreover, in numerous instances, PMN submitters have cooperated in addressing EPA's concerns about new chemicals. As of June 30, 1983, there have been more than 140 voluntary informal actions respecting new chemicals, including 42 cases of voluntary testing and 30 cases of voluntary controls. These statistics confirm that a high percentage of the chemicals that enter the PMN process pose low risks and that the process is effectively identifying those few new chemicals that warrant closer attention.

The PMN Rulemaking. In early 1979, EPA began rulemaking proceedings to implement the PMN provisions of Section 5. On May 13, 1983, EPA promulgated final Section 5 rules, including a standardized PMN form and other requirements which were initially scheduled to become effective on

July 12.[1] In June, CMA and others petitioned EPA to stay the effective date of the final rule to provide an opportunity to address a number of substantial industry concerns and to clarify and modify the rule in several respects. On July 11, EPA granted a stay for 60 days "to clarify certain provisions of the rule that have been identified by industry as ambiguous and to consider the need to revise certain other provisions."[2]

CMA has had and continues to have substantial reservations about the practical value of final PMN rules. Experience has demonstrated that the statutory requirements provide a sound basis for day-to-day operation of the PMN program and that rules clarifying or augmenting these requirements are unnecessary. Indeed, as described above, the PMN program has functioned effectively for over 2,500 new chemicals and will continue to do so without final rules. CMA believes that EPA may not have anticipated the burdensome impact which certain provisions of the proposed rules will have if construed and enforced literally. For example, if read literally, EPA's implementation of the R&D exemption provided by Section 5(h)(3) would impose such substantial burdens on the initial synthesis of each R&D chemical, even those produced in miniscule quantities, that the inevitable result would be a substantial impairment of chemical innovation. In addition, CMA believes that key provisions of the rules are ambiguously framed and do not provide clear guidance concerning the steps necessary to satisfy their requirements.[1]

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[1] 48 Fed. Reg. 21722 (May 13, 1983).

[2] 48 Fed. Reg. 31641 (July 11, 1983).

Testing of New Chemicals. One major issue that has been raised in public discussions concerning the implementation of Section 5 is the adequacy of EPA's existing authority to gather information on new chemicals and whether that Section should be amended to authorize general requirements for the development of test data on such chemicals.

Except in certain limited situations, TSCA does not prescribe specific testing requirements for new chemicals. Nevertheless, Section 5(e) creates important incentives to assure that adequate data on such chemicals are available before manufacture. Under this provision, if a PMN lacks sufficient information to permit a reasoned evaluation of the new chemical's health or environmental effects, EPA may prohibit or limit manufacture of the chemical where it (1) may present an unreasonable risk or (2) will have substantial production volume and significant environmental release or human exposure. Thus, to avoid a Section 5(e) order, it is in the PMN submitter's interest to identify and develop the information needed for a reasoned evaluation of the new chemical's health and environmental effects. If such information is not available and a Section 5(e) order is issued, manufacture will be prevented until the necessary data are developed and submitted for EPA's review.

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[1] A comprehensive discussion of the difficulties for industry presented by EPA's PMN rules is contained in the CMA petition filed on June 17, 1983, a copy of which will be made available to this Subcommittee upon request.

EPA's authority under Section 5(e) has a powerful impact on industry's development programs for new chemicals. As a result it is not surprising that EPA has infrequently found it necessary to use its Section 5(e) authority. For virtually all new chemicals, the information contained in the PMN or later supplied voluntarily by the manufacturer, combined with EPA's in-house expertise, has been sufficient for a meaningful risk assessment.[1]

Two factors help explain why EPA has concluded that additional testing is unnecessary for the great majority of new chemicals. First, many new chemicals are minor modifications of existing chemicals that have been used widely and studied extensively. Chemical companies frequently develop new products within narrow and defined families of compounds whose chemical properties are well-understood. For example, a manufacturer may produce a new fatty acid salt from a common amine or react various standard base chemicals with a well-known inorganic or organic acid. Where test data or use experience is available on the existing compound, EPA and the manufacturer can use that information to evaluate the potential health and environmental effects of the new chemical. If the toxicological properties of the existing chemical are well-defined and toxicity is minimal, the new substance will typically not require toxicity testing.

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[1] A recent report, "The Information Content of Premanufacture Notices," prepared by the Congressional Office of Technology Assessment, verifies that compliance by industry with PMN information submission requirements has been excellent. The report limited its inquiry to a review of the types and amount of information submitted in PMNs and expressly disclaimed any ability, based on the findings of the report, to question the adequacy of that information for purposes of EPA's PMN review. (Report at page 78.) As noted above, responsible EPA officials have expressed the Agency's conclusion that the information which has been submitted has been adequate for PMN review purposes in all but a few cases.

A related factor that has minimized the need for extensive test data is the new substance's potential for environmental release and human exposure. As noted above, exposure considerations play a crucial role in determining whether a company should undertake toxicity testing prior to submitting a PMN or whether EPA should issue a Section 5(e) order requiring toxicity testing. Many PMN chemicals are unlikely to have significant exposure. For example, chemicals manufactured in small quantities often have minimal release into the workplace or the environment. Similarly, substances used as industrial intermediates in a controlled plant setting will often have minimal potential for workplace exposure, particularly where appropriate handling and storage safeguards are observed. In such instances, EPA may properly conclude that the substance's potential risks are minimal and, as a consequence, that extensive testing is unnecessary.

Economic considerations reinforce the need for flexibility in testing new chemicals. Where sufficient information is already available for an informed assessment of a chemical's risks, requiring testing will impose additional costs on the manufacturer without any offsetting benefit to the public. Because many new chemicals are initially manufactured in small quantities and have uncertain commercial prospects, the economic burdens imposed by unnecessary testing could eliminate potentially important new products and impede technological innovation. EPA's own contractor has concluded that the direct costs of preparing and filing PMNs -- which average approximately $7,500 per chemical -- can have a seriously inhibiting impact on the development of new chemicals.[1] The costs imposed by comprehensive testing dwarf the other expenses associated with PMN review and would create major additional disincentives to introduce new products.[2]

TSCA is designed so that the PMN process is not the only opportunity for reviewing a new chemical. EPA has numerous statutory mechanisms for acquiring further information about the potential riskr of a new chemical after manufacture has begun. For example, the Agency may promulgate a test rule under Section 4, a significant new use rule under Section 5(a)(2), or a reporting rule under Section 8. These opportunities to obtain additional data later in a chemical's commercial life-cycle lessen the need for comprehensive premanufacture testing, especially since the cost of unjustified testing prior to commercialization may eliminate potentially important and beneficial new chemicals.

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[1] Authur D. Little, Inc., Impact of TSCA Proposed Premanufacture Notification Requirements, at V-17 (1978).

[2] For example, EPA's own estimates show that full testing in accordance with the Minimum Premarketing Set of Data (MPD) could cost between $50,000 and $100,000. 46 Fed. Reg. 8986 (January 27, 1981).

Some critics of EPA's PMN program have drawn inappropriate comparisons between Section 5 of TSCA and the European Economic Community (EEC) Sixth Amendment, which requires new chemicals to undergo a rigid "base set" of tests. These comparisons fail to take into account the differing approaches of the Sixth Amendment and TSCA. The EEC Sixth Amendment responds to a unique problem -- the need for uniform regulatory requirements among the diverse political systems in the European Community -- that has little relevance in the United States. Moreover, in contrast to TSCA's focus on premanufacture notification for all new chemicals, the Sixth Amendment does not apply to new chemicals unless they are marketed commercially outside the manufacturing company and includes other exemptions that exclude most of the chemicals that are subject to Section 5 of TSCA from the Sixth Amendment's "base set" testing requirements. EPA has estimated that these exclusions would cover 80 percent of the PMNs submitted under TSCA.[1]

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[1] Memorandum from Don R. Clay to Dr. John Todhunter, December 23, 1981.

Equally important, in contrast to the Sixth Amendment, TSCA permits manufacturers to tailor the nature and scope of premanufacture testing to the unique properties of particular new chemicals. Thus, testing under TSCA can be more focused, relevant and cost-effective than testing under a "base set" approach. At the same time, where the criteria of Section 5(e) are met, TSCA gives EPA authority to require additional testing if the information available to the Agency is inadequate for a reasoned risk assessment. Thus, TSCA authorizes EPA to require companies to develop additional data where necessary to protect health and the environment, yet provides an important degree of flexibility and judgment that the Sixth Amendment lacks.

TSCA's PMN requirements have been functioning effectively for nearly four years. The Sixth Amendment, by contrast, has not yet been fully implemented by the Member States; to date, very few premarketing notices containing the results of "base set" testing have been submitted to European national authorities. It would be unwarranted for the United States to abandon a regulatory system of demonstrated effectiveness in favor of a "base set" approach that is unproven and could not be added to TSCA without distorting the basic structure of the Act.

PMN Exemptions. Based on its experience in implementing the PMN process, EPA has proposed to grant limited exemptions under Section 5(h)(4) to three classes of chemicals

-- low-volume substances, site-limited intermediates, and non-reactive polymers. EPA's exemption proposal derives from the Agency's recognition that these chemicals typically present low risks. By streamlining the PMN process for such chemicals, EPA's exemption rule would reduce the sizable barriers to innovation that exist under the present PMN process. Without increased risks to health and the environment, this easing of regulatory burdens would stimulate the introduction of more new chemicals and contribute significantly to economic growth.

The chemicals covered by EPA's exemption proposal would not be excluded from regulation under TSCA or even from new chemical review under Section 5. Rather, the exemption rule would simply reduce the delay and paperwork entailed by EPA review. Exemption applicants would still have to file a notice with EPA and the Agency would continue to evaluate all exempt chemicals before the start of production. Moreover, before any exempt chemical could be manufactured outside the terms of the exemption, a PMN would have to be submitted and EPA would conduct a second, in-depth evaluation of the chemical's risks. Finally, not all low-volume chemicals and site-limited intermediates would qualify for exemption under EPA's rule. These chemicals would receive exemptions only if they meet stringent criteria to assure that they present minimal risks to health and the environment. For example, low-volume chemicals manufactured in quantities of over 1,000 kilograms per year (kg/yr) and all site-limited intermediates would be ineligible for exemption if there are grounds for suspecting that they may cause carcinogenic or teratogenic effects.

Some observers have emphasized the differences between the TSCA exemption proposals and the exemption provisions of the EEC Sixth Amendment. These differences, however, reflect the contrasting approaches of the two regulatory schemes. The Sixth Amendment contains unconditional exemptions for certain defined categories of chemicals. TSCA, on the other hand, relies on EPA to define appropriate exemption categories on the basis of the "no unreasonable risk" standard of Section 5(h)(4).

The Sixth Amendment, for example, excludes all polymers manufactured from existing monomers. EPA's proposal, by contrast, covers only those polymers that, because of high molecular weight or other characteristics, present insignificant risks. Similarly, some EEC Member Countries appear to be interpreting the Sixth Amendment to exclude all new chemicals which are not shipped in commerce within the EEC and are instead used solely within a firm's own operations. The EPA proposal, by contrast, is restricted to site-limited intermediates, a narrower class of compounds.

EPA's low-volume exemption covers chemicals with annual production volumes of up to 10,000 kg/yr., while the comparable EEC exemption is limited to chemicals with annual production volumes of 1,000 kg or less. The EPA proposal, however, contains important safeguards that the Sixth Amendment lacks. Exempt chemicals must satisfy EPA's stringent criteria for low toxicity; these criteria must be applied by a qualified expert; and an exemption notice must be submitted to EPA at least 14 days before production begins. These additional safeguards more than offset the higher production volume threshold included in the EPA proposal.

CMA has supported PMN exemptions as a constructive and responsible method of reducing regulatory burdens while ensuring a healthy and safe workplace and environment. Nevertheless, CMA has expressed disappointment with certain aspects of the Agency's exemption proposals. EPA's proposed scheme for exempting polymers, for example, is unnecessarily restrictive and would burden industry with notification and record-keeping requirements that could eliminate any benefits of the exemption. Similarly, EPA's rigid approach to the role of the qualified expert could deter small companies from taking advantage of the exemption process and result in needlessly complex evaluations of chemicals that present very low risks. As EPA's draft final exemption rule for site-limited intermediates and low-volume chemicals has been reported in the trade press, it is encumbered by so many unnecessarily burdensome restrictions as to render the exemption unworkable and of little or no benefit to the PMN review process. CMA hopes that EPA will address these problems responsively in its final exemption rules.

In sum, Section 5 is functioning effectively to screen all new chemicals and to identify those few new substances that warrant closer attention. Thus, the implementation of Section 5 clearly is accomplishing the Congressional purpose of the provision. The statute in its current form provides EPA with adequate authority to require additional testing where needed and EPA is in fact exercising this authority in those circumstances where it is appropriate. Preservation of the present statutory scheme, coupled with the development of PMN exemptions for low-risk classes of chemicals, will further the achievement of the statutory goals in an effective yet realistic and balanced manner.

II. TESTING OF EXISTING CHEMICALS

A major purpose of TSCA is to develop adequate test data on the human health and environmental effects of commercially established chemicals. Section 4 is designed to provide EPA with sufficient rulemaking authority to require the development of necessary test data by industry while avoiding duplicative testing and distributing testing costs in a manner that will avoid placing any one segment of the industry at a competitive disadvantage. The objectives are being met both by EPA's successful implementation of Section 4 and by independent industry and government testing initiatives.

Status of EPA's Testing Program. Section 4(e) of TSCA establishes an Interagency Testing Committee (ITC), comprised of representatives from several federal agencies, to assist EPA in identifying chemicals that should receive priority consideration for testing. During the twelve-month period following an ITC designation, EPA must either propose a test rule under Section 4 or determine that such a rule is unnecessary. In the past, EPA was slow to respond to the ITC's designations. As a result, in 1981, a district court entered an order establishing a schedule for EPA action on the first five ITC reports. During the last two years, EPA has made substantial progress in meeting this schedule. As of July 11, 1983, EPA has announced preliminary or final testing decisions on 14 categories and 29 individual chemicals. The Agency is also now responding to all new ITC designations with the 12-month statutory deadline.

In addition to acting promptly on the ITC's testing designations, EPA has taken other important steps to implement Section 4. The Agency has published an ambitious set of guidelines that recommend test methodologies for the major human health and environmental effects studies that may be performed under Section 4. These guidelines should be useful in promoting negotiated testing agreements and will be helpful in drafting Section 4 rules.[1] In addition, EPA has published a rule for granting exemptions from test requirements and requiring the reimbursement of test costs.[1] Workable and fair procedures for the financial aspects of testing have substantial value in achieving TSCA's testing goals.

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[1] With United States support, the Organization of Economic Cooperation and Development (OECD) has adopted a Decision providing for the mutual acceptance of data by the major industrialized nations and establishing recommended test guidelines and good laboratory practice standards for health and environmental studies. Coupled with the TSCA guidelines, the OECD recommendations should help promote cost-effective, high quality toxicological testing.

Importance of Negotiated Testing. Cooperative action by EPA and industry has played an increasingly important role in achieving Section 4's testing objectives. To date, testing agreements had been negotiated for two categories of chemicals and 12 individual compounds.[2] For several chemicals, testing is underway and some test results have already been submitted to EPA. Testing on the remaining chemicals will begin shortly. EPA recently stated that during 1982 it received 95 individual studies based on negotiated test agreements. According to the Agency, an additional 195 studies are expected in 1983 and 250 in 1984.

Some critics have questioned whether industry will abide by negotiated agreements. However, these agreements represent a written, public commitment by the firms involved to conduct testing. Failure to honor such commitments would detract from their credibility and jeopardize their relationships with EPA, customers and the public. Accordingly, the chemical industry has important incentives to insure that negotiated test programs are fully performed. In the unlikely event that firms fail to adhere to a negotiated agreement, EPA can use its rulemaking authority to compel testing.[1]

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[1] 48 Fed. Reg. 31786 (July 11, 1983).

[2] 48 Fed. Reg. 32730 (July 18, 1983) (4-chlorobenzotrifloride); 48 Fed. Reg. 23098 (May 23, 1983) (formamide); 48 Fed. Reg. 727 (January 6, 1983) (isophorone); 48 Fed. Reg. 725 (January 6, 1983) (acrylamide); 48 Fed. Reg. 717 (January 6, 1983) (antimony metal, antimony trioxide, and antimony sulfide); 47 Fed. Reg. 58025 (Dec. 29, 1982) (methyl isobutyl ketone and methyl ethyl ketone); 47 Fed. Reg. 58020 (Dec. 29, 1982) (acetonitrile); 47 Fed. Reg. 18172 (April 28, 1982) (2-chlorotoluene); 47 Fed. Reg. 1017 (January 8, 1982) (chlorinated paraffins); 46 Fed. Reg. 54487 (October 30, 1981) (butyl glycolyl butyl phthalate); 46 Fed. Reg. 53775 (October 30, 1981) (alkyl phthalates and benzyl butyl phthalate).

Negotiated test programs include many of the same safeguards as test rules. To date, all testing agreements have contained detailed test protocols and specific schedules for developing data and submitting test results to EPA. Moreover, the development of negotiated test programs is an open process which encourages public involvement at several different stages. Initially, the Agency holds public meetings, announced in the Federal Register, to discuss its tentative plans for responding to an ITC designation. Once industry has submitted a testing program that EPA considers satisfactory, the Agency publishes a Federal Register notice announcing its preliminary acceptance of the program, explaining why the program meets the needs identified by the ITC, and inviting interested persons to comment on the program's acceptability.[1] If EPA decides to proceed with final acceptance of a program, it publishes a second Federal Register notice announcing its decision and responding to all comments it has received.

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[1] In its most recent Federal Register notice accepting a negotiated testing program, EPA has emphatically rejected the criticism that enforcement concerns argue against acceptance of negotiated programs. 48 Fed. Reg. at 32730-32731.

Industry testing proposals submitted to EPA to date have explicitly stated that the results of testing will be disclosed promptly to EPA. Once test data are submitted to EPA, they have the status of health and safety studies under Section 14(b) of TSCA and must be disclosed to the public on request. Upon receiving data from a negotiated testing program, EPA publishes a Federal Register notice announcing the availability of test results. One such notice has been published for three test programs.[2] Thus, the public has a full opportunity to review the data generated by negotiated testing and to provide EPA with comments on the significance of test results.

The development of negotiated testing programs is more efficient and flexible than promulgating test rules. Consequently, testing conducted on a negotiated basis begins much sooner, and requires a smaller expenditure of EPA and industry resources, than testing commenced after rulemaking proceedings. By EPA's own estimate, the negotiation process results in the initiation of testing approximately one to three years earlier than under a test rule.[1] The negotiation process also occurs in an informal, non-adversarial atmosphere which is conducive to resolving complex scientific issues. Thus, the determination of testing needs and selection of test procedures can be accomplished more effectively than in a rulemaking proceeding.

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[1] Environmental groups and others have in fact submitted such comments.

[2] 48 Fed. Reg. 12124 (chlorinated paraffins, 2-chlorotoluene, and alkyl phthalates) (March 23, 1983). See also 47 Fed. Reg. 36958 (August 24, 1982) (chlorinated paraffins and 2-chlorotoluene).

If negotiation does not result in a satisfactory testing agreement, EPA retains the authority to propose a test rule. EPA has not hesitated to use that authority where appropriate. As of July 11, 1983, the Agency has published 12 test rule proposals and 2 advance notices of proposed rulemaking under Section 4.[2] Final rules for some chemicals are expected to be issued shortly.[3]

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[1] EPA FY 1984 Budget, pages 53-54.

[2] 48 Fed. Reg. 31812 (July 11, 1983) (cresols); 48 Fed. Reg. 30699 (July 5, 1983) (mesityl oxide); 48 Fed. Reg. 23088 (May 23, 1983) (ethyltoluenes, trimethylbenzenes, and, C aromatic hydrocarbon fraction); 48 Fed. Reg. 23080 (May 23, 1983) (biphenyl); 47 Fed. Reg. 18386 (April 29, 1982) (proposed test rule on diethylenetriamine); 47 Fed. Reg. 973 (January 8, 1982) (ANPR on phenylenediamines); 46 Fed. Reg. 53704 (October 30, 1981) (ANPR on fluoroalkenes); 46 Fed. Reg. 30300 (June 5, 1981) (proposed test rule on dichloromethane, nitrobenzene, and 1,1,1-trichloroethane); 45 Fed. Reg. 48524 (July 18, 1980) (proposed test rule on chloromethane and chlorinated benzenes).

[3] It should be noted that, in contrast to negotiated agreements, no testing is yet being conducted under test rules. This illustrates the greater efficiency of the negotiation process.

In a recent report, the General Accounting Office (GAO) emphasized that "to compel testing under Section 4, where otherwise acceptable voluntary testing is planned, would . . . be an inefficient use of EPA's resources and inconsistent with the Congress' desire to avoid duplicative and unnecessary testing." GAO also concluded that, under TSCA, "authority exists for EPA to negotiate voluntary testing agreements because the agreements are reasonably consistent with the significant purposes of Section 4 -- to ensure that industry at its own expense develops adequate data to assess a chemical substance's or mixture's risk to health or the environment."[1]

Other Testing Activities. Testing conducted under Section 4 is only one source of data on the health and environmental effects of existing chemicals. Industry testing programs independent of TSCA are extensive. These include studies conducted or sponsored by individual companies, groups of companies, and the Chemical Industry Institute of Toxicology (CIIT). Contract testing laboratories, in-house company facilities, and academic institutions are all involved in these programs. The scope of industry-sponsored testing is extensive. Since 1976, CIIT's research, evaluation and testing program has investigated or reviwed 40 chemicals. CMA administers 29 programs that are sponsored by individual companies, not all of which are members of CMA. Ten of the programs address over 60 chemicals that are included in 16 ITC designations. Such testing efforts will make a substantial contribution to TSCA's goal of assessing the health and environmental effects of chemicals.

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[1] General Accounting Office, EPA Implementation of Selected Aspects of the Toxic Substances Control Act, December 7, 1982, at page 4.

Additional testing is being conducted under governmental auspices. The National Toxicology Program, the National Institute of Environmental Health Sciences, the National Cancer Institute, and the National Center for Toxicological Research are all sponsoring testing and research activities relating to the health effects of industrial chemicals.

In sum, TSCA contains comprehensive authority to require the testing of existing chemicals and EPA is exercising that authority effectively. Simultaneously, the United States chemical industry has continued to place substantial emphasis on voluntary health and environmental testing. As a result, impressive progress is being made in achieving TSCA's objective of expanding the available data-base on the health and environmental effects of existing chemicals.

III. INFORMATION COLLECTION AND DISSEMINATION

Section 8 of TSCA assists EPA in carrying out its regulatory responsibilities under the Act by authorizing the collection and reporting of information relating to the health or environmental effects of chemicals. Section 8's provisions for record-keeping and data collection and dissemination are comprehensive and have few counterparts in the laws of other nations.

To date, reporting requirements under Section 8(a) have been promulgated for three chemicals of immediate concern -- polybrominated biphenyls, tris (2,3-dibromopropyl) phosphate, and asbestos. In addition, EPA has promulgated a broad "preliminary assessment" rule under Section 8(a) which applies to over 250 substances. Collection and review of the production, use, and exposure information already submitted under this rule is a substantial task that is consuming thousands of EPA and industry man-hours.[1] Further, in May and June of this year, EPA added over fifty chemicals to the list of substances subject to the preliminary assessment rule, proposed the addition of another seventeen chemicals to the list, and established an automatic triggering mechanism to add all future ITC designated chemicals to the list.[2]

EPA has also promulgated a final rule under Section 8(d), a provision that provides for the submission of health and safety studies and underlying data. This rule, which applies to more than 300 chemicals, has imposed substantial reporting responsibilities on a major segment of industry and has likewise required a major commitment of industry resources.[1] Recently, EPA has added chemicals to the list for which Section 8(d) reporting is required and has proposed to add others.[2]

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[1] EPA has estimated that 664 reports were submitted under this rule.

[2] 48 Fed. Reg. 28443 (June 22, 1983); 48 Fed. Reg. 22694 and 22697 (May 19, 1983); 48 Fed. Reg. 21294 (May 11, 1983).

Yet another important information-gathering tool created by TSCA is Section 8(e). This provision requires firms to report new information that indicates a substance or mixture may present a substantial risk of injury to health or the environment. To date, EPA has received nearly 500 reports under Section 8(e). These reports have brought to EPA's attention a broad range of toxicological studies, epidemiological data, and other information and have resulted in extensive EPA and industry follow-up activities. These activities have included dissemination of information to other agencies and the public, consideration of further testing or the withdrawal of products, voluntary exposure controls, labeling changes, and investigations by EPA, NIOSH, and other agencies.

While recognizing the important role of information-gathering in the statutory scheme, CMA has periodically expressed concern about EPA's tendency to use its Section 8 authority in an unfocused and overly broad manner. Examples of this tendency include EPA's failure to articulate meaningful criteria for including chemicals in its "preliminary assessment" rule under Section 8(a); the Agency's insistence on automatic reporting under Sections 8(a) and 8(d) for all chemicals designated for testing by the ITC; EPA's broad definition of "health and safety study" under Section 8(d); and provisions of EPA's Section 8(c) proposal that would require reporting of voluminous allegations of adverse reactions without defining the role of this information in EPA's activities under TSCA.

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[1] According to EPA, it has received 4,220 individual studies.

[2] 48 Fed. Reg. 28483 (June 22, 1983); 48 Fed. Reg. 24366 (June 1, 1983).

Unless EPA uses the data it obtains in an effective and timely manner, Section 8 reporting requirements will serve no useful purpose. Since EPA's rules under Section 8 are potentially applicable to a large number of firms and chemicals, it is particularly important that the Agency provide a sound justification for its recordkeeping and reporting requirements and that these requirements be narrowly drawn and cost-effective. An effective mechanism for ordering priorities for information collection should be an important element of EPA's Section 8 programs. CMA urges EPA to strive toward these goals while continuing to use Section 8 to create a sound data base for future regulatory activities under TSCA.

IV. CONTROL OF UNREASONABLE RISKS

Section 6 of TSCA provides EPA with its principal authority for controlling chemical substances or mixtures which have been demonstrated to present an unreasonable risk of injury to human health or the environment. Section 6 authorizes EPA to employ a broad range of control measures, including banning manufacture, prohibiting particular uses, or requiring special labeling. The Agency can act only after rulemaking proceedings in which affected parties have an opportunity to present witness testimony and conduct cross-examination.

Section 6 was intended to be a "safety net" to augment voluntary industry control measures and regulations imposed under other health and environmental laws. The impact of these other activities is therefore an important factor in evaluating EPA's performance under Section 6.

Industry Control Activities. Industry efforts to protect health and the environment have been extensive. Chemical control programs, managed by experienced professionals and specialists, are an integral part of the operations of a major proportion of producers and users of chemicals. As a result of these programs, hazard information is widely distributed to users of chemicals through material safety data sheets (MSDS), labeling, technical bulletins, training programs, and interaction among knowledgeable professionals. In addition, emergency response systems are in place across the industry to respond to spills, explosions, or other incidents.

The extensiveness of these industry programs is confirmed by a recent survey of the U.S. chemical industry conducted for CMA by Peat, Marwick, Mitchell & Co.[1] The survey was completed in December 1982, and covered 112 companies representing 56 percent of the total dollar volume of chemicals sold in the United States. According to the survey, nearly 90 percent of the companies routinely involve senior executives in developing and managing health and environmental programs. One out of every 55 employees of the surveyed companies is a health or environmental specialist, and a total of 12,000 employees are trained to handle emergencies for chemical spills or releases inside and outside of their facilities. Responding companies indicated that they spent a total of $138,000,000 on toxicity testing in 1981, and the value of testing facilities for all respondents was estimated at $255,000,000. The survey also showed that 9 out of 10 companies have established programs to monitor the health of their employees, and virtually all companies use MSDSs to communicate safety information about chemical products.

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[1] An Industry Survey of Chemical Company Activities to Reduce Unreasonable Risk, Prepared for CMA by Peat, Marwick, Mitchell & Co., February 11, 1983.

Impact of Other Laws. Adding to the protection provided by voluntary industry control programs is the comprehensive system of regulatory controls authorized under health and environmental statutes other than TSCA. Environmental releases of hazardous chemicals, for example, are monitored and controlled through the permit-issuing process established under the air, water and solid waste disposal laws implemented by EPA. Similarly, workplace exposure to chemicals is extensively controlled by OSHA. Standards promulgated by OSHA and recommendations issued by the American Conference of Governmental Industrial Hygienists (ACGIH) exist for more than 500 chemicals, and NIOSH criteria documents have been issued for numerous other substances. Indeed, there are some chemicals that are regulated under several laws simultaneously. Vinyl chloride, for example, is controlled under nine significant regulations enforced by four separate agencies.

Chemical Control Actions Under TSCA. Implementation of Section 6 of TSCA has supplemented voluntary industry action and regulation under other statutes. EPA's activities under Section 6 to date have focused mainly on chlorofluorocarbons (CFCs), asbestos, and polychlorinated biphenyls (PCBs). In attempting to control these substances, EPA has been forced to confront far-ranging and complex economic and scientific issues. Inevitably, the rulemaking process has placed sizable demands on EPA's resources and required a major investment of time and staff.

In the case of PCBs, EPA's task has been complicated by the intricate provisions of Section 6(e) and protracted court challenges to EPA's original PCB regulations. In view of the health effects data and existing PCB controls, CMA believes that the expenditure of EPA and industry resources on PCB rulemaking and compliance activities has greatly exceeded any possible benefit to the public. It is encouraging, therefore, that the resolution of the remaining PCB regulatory issues may be near at hand. On April 13, two environmental groups, CMA, and other industry representatives jointly submitted to EPA a recommended proposal to resolve all outstanding issues concerning inadvertent generation of PCBs. The proposal, which resulted from lengthy deliberations among the affected parties, provides a reasonable and practical resolution to any public health problem posed by inadvertent PCB generation. On June 3, Don Clay stated in a letter to industry and environmental groups that EPA had decided to use the joint recommendation as a framework for the regulation of inadvertently generated PCBs, and that the Agency would develop and publish for public comment its regulatory proposal later this year.

EPA's Existing Chemicals Program. EPA is also taking significant steps to define and implement a comprehensive program to review existing chemicals for possible action under Section 6. Among the major features of the EPA program are systematic priority-setting, a five-phase process for evaluating possible hazards, decision-points for referring issues to other agencies or EPA offices, careful evaluation of voluntary industry practices, and attention to cost-effective non-regulatory and regulatory approaches. CMA believes that the EPA program is well-designed but is concerned about how some aspects of the program will be implemented. For example, EPA has not yet clarified the contents and purposes of non-regulatory Risk Management Advisories (RMAs) or established clear guidelines for obtaining industry comments on its analyses and conclusions.

As of June 30, 1983, 50 chemicals or categories were in various stages of the existing chemical program; some of these have progressed to the latter stages of EPA's information-gathering and evaluation process. On April 27, 1983, EPA announced initiation of a 180-day regulatory review of 4,4'-methylenedianiline (MDA) under Section 4(f) of TSCA, a provision designed to trigger such a review when information indicates that a chemical presents a significant risk of serious or widespread harm to humans.[1] On May 23, EPA published an advance notice of proposed rulemaking respecting 4,4'-methylene bis (2-chloroaniline) (MOCA) soliciting information on sources of adverse effects, exposure controls, potential substitutes for the chemical in its various uses, and potential economic impact of regulation.[2] It is too soon to predict the outcome of these initiatives or to assess generally the results that will be derived from EPA's initial regulatory assessments of existing chemicals, but as EPA's existing chemicals program becomes fully operational, it should reinforce voluntary industry practices and the extensive array of regulatory controls under other laws.

As EPA proceeds with its existing chemicals program, it will need to construe and implement the requirements of

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[1] 48 Fed. Reg. 19078 (April 27, 1983).

[2] 48 Fed. Reg. 22959 (May 23, 1983).

Section 9, which govern the relationship between EPA's authority under TSCA and the coverage of other laws for the protection of health and the environment. Section 9 was included in TSCA to avoid duplicative and potentially conflicting activities by different agencies, while allowing EPA to take effective action against unreasonable risks that are not being controlled under other laws. Although EPA has not yet applied Section 9, CMA believes this provision will be increasingly important in minimizing wasteful duplication of effort by EPA's Office of Toxic Substances and other governmental bodies with health and environmental responsibilities.

In sum, a sound framework is emerging for managing the risks associated with existing chemicals. Industry-initiated control programs are numerous and are significantly protecting human health and the environment. The comprehensive health and environmental laws implemented by EPA and other agencies reinforce this protection. These laws provide for extensive regulation of workplace practices, air emissions, water discharges, and solid waste disposal. TSCA's broadly-framed control provisions provide an additional level of protection against unreasonable risks that cannot be effectively addressed under other laws.

CONCLUSION

After six years, there is tangible evidence that TSCA constitutes a sound framework for assessing and controlling potential risks associated with chemicals. EPA's TSCA programs have not always met with industry approval, but the Agency has progressed toward implementing the Act in a practical, reasonable and effective manner. Continued improvement in EPA's implementation of TSCA can best be achieved by prudent administration of the law rather than by statutory revision.

CMA

CHEMICAL MANUFACTURERS ASSOCIATION

WILLIAM M. STOVER
Vice President
Government Relations

August 19, 1983

The Honorable David Durenberger
Chairman, Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment
and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

During your Subcommittee hearing on toxic substances oversight August 1, 1983, you invited the witnesses to expand on their responses to your list of 5 questions by submitting more detailed answers in writing. Enclosed are the written responses of Dr. Jerry Smith, Director of Toxicology for the Rohm & Haas Company, who testified on behalf of the Chemical Manufacturers Association. We would appreciate your inserting them in the record of the hearing.

Kind regards.

Sincerely,

William M Stover

Enclosure

Formerly Manufacturing Chemists Association—Serving the Chemical Industry Since 1872.
2501 M Street, NW • Washington, DC 20037 • Telephone 202/887-1122 • Telex 89617 (CMA WSH)

August 18, 1983

RESPONSE TO QUESTIONS OF SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT

At the August 1 hearing of the Subcommittee on Toxic Substances and Environmental Oversight of the Senate Committee on Environment and Public Works, Senator Durenberger raised a series of issues relating to the implementation of TSCA and asked the witnesses for their comments. CMA has carefully considered these issues and remains convinced that, in its current form, TSCA is working effectively and its revision is unnecessary. CMA's specific comments on the five issues raised by Chairman Durenberger are as follows:

1. Categories For New Chemical Testing.

Issue. Should specific "high risk" categories of new chemicals or uses be identified and the burden placed on manufacturers of chemicals within these categories to develop test data or exposure controls which demonstrate the absence of an unreasonable risk? Should "low risk" categories of new chemicals be exempt from PMN review by law?

CMA Response. CMA has serious reservations about defining high risk categories of chemicals in Section 5 itself. Identifying such categories will inevitably be complex and time-consuming. Since toxicological and exposure considerations will play an important role in this process, a considerable amount of background information will be necessary. Evaluating this information will call for considerable expertise in toxicology and risk assessment.

Defining "high risk" categories will also be controversial and involve a considerable risk of error. Where a category is defined in over-inclusive terms, it will include compounds that pose a minimal risk to health or the environment. If all new chemicals within such categories must be subject to extensive testing or stringent controls before commercialization, the result could be a considerable and unwarranted adverse impact on innovation. In this event, society will needlessly lose the benefit of many potentially beneficial new substances.

If it is necessary at all, the task of defining high risk categories should be performed by an administrative body like EPA. EPA has the necessary expertise to grapple with the controversial issues involved in establishing categories, and the Agency's rulemaking procedures will assure that all relevant data and viewpoints are considered.

TSCA already provides EPA with authority to designate categories of new chemicals that may present unreasonable risks and to require that chemicals in these categories undergo intensive evaluation before manufacture. Under Section 5(b)(4)(A), EPA may, by rule, compile a list of chemical substances whose manufacture, processing, distribution, use or disposal may present an unreasonable risk of injury to health or the environment. Under Section 26(c), this list may include categories of new chemicals where EPA believes substances within such categories possess sufficient similarity to warrant uniform treatment. Once a category has been included in EPA's "risk list", Section 5(b)(2) provides that PMNs for chemicals within the category must include test data which demonstrate that proposed commercial activities involving the chemical "will not present an unreasonable risk of injury to health or the environment." If EPA concludes that the manufacturer has not satisfied its burden of proof, the Agency may impose appropriate restrictions.

In the past, EPA has been reluctant to implement Section 5(b)(4) because of the complexity of this provision and the other demands on its resources. Recently, however, EPA has expressed an interest in identifying categories of new chemicals for inclusion in the "risk list."1/ Because of the difficult judgments involved in establishing such categories, CMA intends to review any EPA proposals carefully. It is possible that, over time, EPA may discover that use of the "risk list" represents a less effective approach to the testing of new chemicals than a carefully targeted application of Section 5(e) to substances of concern. Certainly, Section 5(e) has proven adequate to meet EPA's testing needs for new chemicals to date.

The Subcommittee has also asked for comments on the wisdom of amending TSCA so that "low risk" categories of substances are exempted from PMN review by law. The delineation of suitable exemption categories likewise requires considerable

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1/ Office of Toxic Substances, Environmental Protection Agency, TSCA Priorities and Progress (July 1983).

scientific expertise and administrative judgment. For this reason, EPA and not Congress is the appropriate body to establish such exemptions.

Section 5(h)(4) of the current law authorizes EPA to exempt specified chemicals from all or some of the requirements for PMN review upon a finding of no-unreasonable-risk. Under Section 26(c), EPA's exemption authority can be exercised for categories of new substances as well as individual compounds. EPA is currently conducting rulemaking proceedings under Section 5(h)(4) to exempt certain intermediates, low-volume chemicals and polymers from full PMN review. While CMA does not support all aspects of EPA's proposal, it believes that implementation of Section 5(h)(4), rather than statutory change, is the proper vehicle for reducing regulatory burdens on low-risk new chemicals. CMA would be pleased to furnish the Subcommittee with fuller details concerning the effective implementation of Section 5(h)(4) by providing copies of its petition to develop an exemption rule for low-risk new chemicals and related background papers.

2. Follow-up Testing

Issue. Should a rebuttable presumption be established that all new chemicals must undergo additional testing upon either attaining specified post-market production levels and/or the passage of specified periods of time?

CMA Response. CMA agrees that follow-up monitoring of new chemicals after PMN review is desirable and that additional testing of some substances may be warranted based on their commercial growth and increase in exposure potential. The present statutory provisions, however, provide a better vehicle for such follow-up than universal testing requirements arbitrarily triggered by increases in production volume or other inflexible criteria.

TSCA now provides EPA with extensive authority to monitor the commercial development of new chemicals that have completed PMN review. First, under Section 8, EPA may promulgate rules which require periodic reporting of information (such as uses and production volume) for new chemicals that have entered commercialization. Second, Section 5(a)(2) authorizes EPA to promulgate "significant new use rules" (or SNURs) for new chemicals that raise particular health or environmental concerns. Under such SNURs, manufacturers would be unable to initiate production for specified uses without submitting a notice to EPA at least 90 days before the start of manufacture. Upon receiving this notice, EPA could prohibit or limit manufacture under Section 5(e) until the test data specified by the Agency have been developed and submitted for review. Finally, Section 4 of TSCA allows EPA to prescribe testing requirements for new and existing chemicals that may present an unreasonable risk of injury or have the potential for significant human exposure or substantial environmental release. Like Sections 8 and 5(a)(2), Section 4 is potentially applicable to entire categories as well as to individual compounds.

The follow-up mechanisms in the present statute allow EPA to focus on individual compounds or categories that, because of toxicity or exposure considerations, warrant close scrutiny. This reasoned, selective approach offers distinct advantages over automatic follow-up requirements. Many new chemicals will need little or no follow-up monitoring -- either because their exposure potential will not significantly increase over time or because their human health and environmental effects are well-characterized and their capacity for harm is small. Requiring follow-up monitoring for such chemicals would impose unjustified costs on industry and result in an unproductive expenditure of EPA resources.

Any automatic triggers which are used to initiate follow-up testing or reporting requirements would not be justified for many of the new chemicals now subject to TSCA's PMN requirements. In isolation, for example, production volume is a poor indicator of the need for testing because it corresponds neither to a chemical's toxicity nor to its exposure potential. Much more meaningful indices of the need for testing include the chemical's potential for human exposure or environmental release, the adequacy of existing test data, the type and level of biological activity associated with the chemical's structure, and the chemical's physical and chemical properties. These factors may differ dramatically from chemical to chemical. Thus, even if manufacturers of particular chemicals had an opportunity to rebut a presumption that testing is needed, the time and effort required to evaluate each chemical would itself place major burdens on industry and EPA. For this reason, the best approach -- embodied in the current statutory scheme -- is for EPA to select those specific chemicals or categories which warrant follow-up and then to develop suitable testing or reporting requirements.

EPA is actively exploring the follow-up mechanisms available under the current statute.[1/] The Agency is implementing a flexible yet effective follow-up program targeted at chemicals of concern identified during the Agency's initial PMN review. Depending on the chemical, EPA plans to use SNURs under Section 5(a)(2), reporting rules under Section 8, or test rules under Section 4. Over time, CMA believes that EPA's follow-up program will further prove its effectiveness and confirm that statutory revision is not needed.

3. Existing Chemical Priority Testing

Issue. Should the ITC screening process be improved by requiring the submission of more production and use data? Should EPA be authorized to require testing under Section 4 by administrative order rather than by rule?

CMA Response. Critics of the present ITC evaluation process overlook the limited role of the ITC in TSCA's testing scheme. The ITC's function is to assist EPA in setting testing priorities by designating chemicals for consideration under Section 4; EPA has the responsibility for testing decisions based on its analysis of the ITC's recommendations and all other

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1/ EPA's recent document TSCA Priorities and Progress describes this follow-up program at pages 16-19.

relevant information. Since the ITC performs a screening function, some divergence between ITC recommendations and EPA's ultimate testing decisions is to be expected. Thus, EPA's occasional decision not to require testing specified by the ITC does not necessarily mean that the ITC is failing to discharge its responsibilities.

Because of the ITC's screening function, it would be counterproductive for the ITC to adopt formalized data-gathering procedures. Nevertheless, the ITC should have access to essential production/use information on chemicals under consideration for testing. In the past, the ITC has not always made maximum effort to gather such information. Recently, however, substantial improvements have been made in this regard. The ITC now regularly publishes Federal Register notices which contain a "candidate list" of chemicals under evaluation for possible designation and request the submission of background information by affected manufacturers and processors.[1] To allay industry concerns, the ITC's contractors have developed procedures for safeguarding confidential information. As a result of these steps, industry has generally been responsive to the ITC's requests for data, and the quality of the information available to the ITC has improved significantly.

Since the ITC has been successful in obtaining adequate industry cooperation on a voluntary basis, CMA sees no need to authorize the ITC to prescribe formal reporting requirements. Once the ITC has designated substances for EPA consideration under Section 4, current Agency rules provide for the automatic triggering of reporting requirements under Sections 8(a) and 8(d) of TSCA.[1/] Thus, EPA -- which has ultimate responsibility for testing decisions -- will obtain any additional data on testing candidates that is necessary before initiating rulemaking proceedings under Section 4.

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[1] 47 Fed. Reg. 8244 (February 25, 1982).

CMA likewise sees no need to authorize EPA to require testing by administrative order rather than rule. Rulemaking proceedings under the Administrative Procedure Act (APA) represent a time-honored method for adopting regulatory requirements that affect entire segments of industry. Experience has demonstrated that the APA's rulemaking procedures strike the best possible balance between the objectives of public participation, administrative efficiency and reasoned decision-making. EPA uses informal rulemaking proceedings under virtually every other statute it administers, and rulemaking plays a major role in the activities of every other health and safety agency. There is absolutely no evidence that delays in completing the rulemaking process have impaired EPA's ability to protect health or the environment. Indeed, if evidence emerged that a testing candidate posed a serious risk, EPA could invoke the "imminent hazard"

[1/] 40 C.F.R. § 712.30, 48 Fed. Reg. 21294 (May 11, 1983) (Section 8(a)); 40 C.F.R. § 716.18, 47 Fed. Reg. 38780 (September 2, 1982) (Section 8(d)).

provisions of Section 7 before the completion of the rulemaking process.

Administrative orders simply would not be a workable mechanism for developing testing requirements. Such orders are typically used for licensing or rate-making decisions which are highly factual in nature and affect a small handful of companies. Moreover, under the APA, issuing an administrative order may involve cumbersome procedures -- such as formal evidentiary hearings -- that are unnecessary in informal rulemaking. Thus, requiring testing by rule may actually be more efficient and less time-consuming than using administrative orders.

As CMA stressed in its testimony, the delays associated with the rulemaking process can be avoided by the continued use of negotiated testing programs. By EPA's estimate, testing conducted under such programs can be initiated between 18 and 24 months earlier than testing required by rule. Moreover, the negotiation process is less resource-intensive than rulemaking and represents an excellent vehicle for reaching agreement on complex scientific issues. If the Subcommittee's concern is to minimize delay, greater use of the negotiation process represents a far more promising approach than elimination of Section 4's rulemaking procedures.

4. Confidential Business Information

Issue. Should EPA require all confidentiality claims to be justified and allow state programs access to confidential data?

CMA Response. Section 14 of TSCA already contains stringent criteria for evaluating confidentiality claims. Under Section 14(a), EPA is authorized to accord confidential treatment to data submitted by industry only if the data qualify as trade secret or confidential commercial information within the meaning of Exemption 4 of the Freedom of Information Act (FOIA). Over the years, Exemption 4's confidentiality requirements have been applied by several agencies and interpreted in numerous court decisions. It is well established that, in order to obtain confidential treatment, the manufacturer must be able to demonstrate that he will suffer concrete, substantial competitive injury if the information in question is disclosed.[1/] Frivolous or unjustified confidentiality claims must be rejected.

EPA has implemented Section 14 of TSCA in accordance with this approach. Under EPA's regulations, before upholding any confidentiality claim and denying requests for disclosure, the Agency requires manufacturers to demonstrate the commercial sensitivity of the information to be withheld.[2/] For certain categories of information like chemical identity, the Agency has insisted that manufacturers meet an unusually high burden of proof by answering a detailed set of questions relating to every

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[1/] National Parks and Conservation Association v. Kleppe, 547 F.2d 683 (D.C. Cir. 1976); Union Oil Co. v. FPC, 542 F.2d 1036 (9th Cir. 1976).

[2/] 40 C.F.R. § 2.204.

conceivable aspect of confidentiality.[1] Thus, as implemented by EPA, Section 14 already limits confidential treatment to information of genuine commercial importance; modifying Section 14 for this purpose is unnecessary.

Except for claims relating to chemical identity, current EPA regulations do not require manufacturers to substantiate their right to confidential treatment at the time information is submitted to the Agency. Rather, the Agency requires such substantiation when the information is requested under the FOIA or is under consideration for disclosure for some other reason. In abandoning its original requirement of advance substantiation, EPA emphasized the burden that this requirement placed on industry and the sparse number of FOIA requests filed for information submitted under TSCA.[2] In addition to these factors, it should be noted that advance substantiation is not required under other health or safety statutes implemented by EPA or other agencies.

Critics of EPA's confidentiality procedures have also emphasized that confidentiality claims have been made for a large mount of information included in PMNs and have asserted that many of these claims are spurious and unjustified. However, it s hardly surprising that manufacturers would seek to safeguard roduction, use and identity information for new chemicals.

/ 40 C.F.R. § 720.85 (final PMN rule).

' 47 Fed. Reg. 28969 (July 2, 1982).

These chemicals often represent highly innovative improvements over existing compounds, and disclosure of their composition and functions before commercialization could well deprive manufacturers of important competitive advantages. EPA's critics have presented no concrete evidence that the confidentiality claims of PMN submitters have impaired the rights of FOIA requesters or prevented EPA from conducting a thorough review of new chemicals.

It should be emphasized that, even where information meets established legal standards for confidential treatment, EPA has authority to disclose the information for legitimate regulatory purposes. Under Section 14(b), EPA cannot accord confidentiality to "health and safety studies" except under very narrow conditions. And under Section 14(a), EPA may disclose confidential information for a variety of regulatory functions, including the need to protect health or the environment against an unreasonable risk of injury. Thus, EPA already possesses considerable flexibility in the handling of confidential information. Statutory changes to provide EPA with additional flexibility are unwarranted.

Consistent with the protections of Section 14(a), CMA does not oppose the disclosure of confidential information to state officials when that information will aid in implementing state regulatory programs for the protection of health or the environment. Based on its authority under Section 14(a)(3), EPA has already made confidential data available to state authorities. Where confidential information is disclosed outside EPA, however, adequate safeguards to maintain its confidential status should be required. Thus, before transferring any confidential information to states, EPA should satisfy itself that the state has established an adequate program for confidentiality protection.

5. Industry Funding of Government Testing Programs

Issue. Should the cost of government-sponsored testing programs be transferred to industry by imposing a uniform permit fee on manufacturers and users of the chemicals in question?

CMA Response. Government-sponsored testing programs should attempt to satisfy long-term research needs, while testing programs supported by industry should seek to develop data to assess the risks of substances with widespread human and environmental exposure. In view of the differing objectives of industry and government-sponsored testing, it would be unwarranted to impose the costs of government programs on chemical manufacturers. As long-term research projects, these programs meet general societal needs and should therefore be supported by the public at large.

The chemical industry is committed to conducting sufficient testing to assess the health and environmental risks of its products. Industry-financed testing programs devoted to this goal are already extensive. Testing required under Section 4 of TSCA must be financed by the manufacturers and/or processors of the chemicals involved. According to EPA, several hundred studies on Section 4 chemicals are already underway. Moreover, numerous testing programs independent of TSCA have been initiated under the sponsorship of individual companies, groups of companies and the Chemical Industry Institute of Toxicology (CIIT).

The aggregate costs associated with industry-sponsored testing activities are substantial. A recent survey conducted for CMA revealed that the participating companies (which represent 56 percent of the total dollar volume of chemicals sold in the United States) spent a total of $138 million on toxicity testing in 1981 and operated testing facilities with an estimated value of $255 million. The extensive scope of industry-sponsored testing demonstrates that chemical manufacturers are already committing substantial resources to meeting the testing needs of regulatory agencies, workers, customers and the general public. It would be unjustified to add to these burdens by requiring industry to bear the costs of testing conducted under government auspices as well.

INDEPENDENCE MALL WEST PHILADELPHIA, PA 19105 U.S.A. TELEPHONE [illegible]
CABLE ADDRESS ROHMHAAS TELEX 845-247 TWX [illegible]

REPLY TO
RESEARCH LABORATORIES
727 NORRISTOWN ROAD
SPRING HOUSE, PA 19477
(215) 641-7000
(215) CH 2-0400

ROHM AND HAAS
COMPANY

November 9, 1983

83-169

The Honorable Dave Durenberger
Chairman
Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environmental and Public Works
United States Senate
Washington, DC 20510

Dear Senator Durenberger:

Attached is Rohm and Haas's response to the follow-up questions to my testimony before the Subcommittee on Toxic Substances and Environmental Oversight.

The complexities of the issues involved and Rohm and Haas activity in areas of product safety and regulation, in addition to TSCA, preclude crisp, precise answers to the very important questions you have asked. Therefore, for some questions I have expanded the answers.

If your schedule permits, I would be pleased to expand further on the answers by having you visit our Toxicology Laboratory. In our laboratory, you could observe firsthand how we address daily the problems of structure-activity relationships, assessment program design, test design, evaluation of data, and assessment of risk and risk management.

If our staff or I could be of further service, do not hesitate to call us at (215) 641-7536.

Sincerely,

J. M. Smith, Ph.D., D.A.B.T.
Corporate Director of Toxicology

JMS:cf
Attachment

Response to Questions of Senate Subcommittee on Toxic Substances & Environmental Oversight

by

Jerry M. Smith, Ph.D.
Corporate Director of Toxicology
Rohm and Haas Company

(On behalf of Rohm and Haas Company and the Chemical Manufacturers Association)

Introduction: At Rohm and Haas Company, human health and environmental hazard concerns are not limited to chemicals covered by the Toxic Substances Control Act (TSCA). Thus, our concerns include those of corporate conscience, as well as those covered by other statutes such as the Federal Insecticide Fungicide Rodenticide Act (FIFRA), Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act (RCRA), and the Food, Drug, and Cosmetic Act (FFDCA). Our resonses to the Subcommittee's questions must be viewed with these conderations in mind. We have phrased answers specifically with reference to TSCA wherever possible. Where appropriate, we have added comments general to the chemical industry for the Subcommittee's consideration.

● 1. When Congress enacted TSCA, it was concerned that required testing might overwhelm available testing capacity.

● Did your company expand its laboratory testing capacity and budget for testing at the time TSCA was enacted?

Rohm and Haas Company began developing its "in house" toxicology laboratory late in 1973. Since that time, testing capabilities have been expanded, and staff and facilities have grown to 75 people and 30,000 square feet, respectively. The budget for this function has grown by 3000%, and is currently equal to 10 percent of our total research budget. Note that this budget includes both in-house and contract toxicology testing expenditures.

- If so, has that capacity been fully utilized?

Yes.

- Do you have any information or impressions about the extent to which the testing capacity of independent laboratories is being utilized at the present time?

I have no hard data about the utilization rate of independent laboratory testing capacity. My impression, however, is that 60% to 80% of the independent facilities are being used. This impression is based on conversations with representatives from independent laboratories, the ease with which we have been able to initiate studies in a timely manner, and the frequency of calls from independent laboratories seeking work for contract testing.

The causes of excess capacity which exist at present are complex. During the late 1970's, industry significantly expanded its in-house testing capability. Many companies either built new toxicological laboratories or enlarged existing facilities. In addition, the Chemical Industry Institute of Toxicology (CIIT) was formed to support research and testing needs of industry as a whole. Because of these developments, studies that might have been performed at contract laboratories have been conducted elsewhere.

Another factor that has contributed to the under-utilization of contract laboratories is the fact that the National Toxicology Program (NTP) and other government agencies have shifted their emphasis away from bioassays, which are time- consuming and require a major commitment of laboratory space, to short-term studies and mechanistic tests, which require fewer resources. Thus, independent laboratories are conducting less testing for the government than they were in the late 1970's.

The under-utilization of contract facilities does not mean, however, that current testing needs are always being met in a satisfactory manner. We still encounter delays in receiving reports from contract laboratories, as do government agencies such as NTP. The Subcomittee should be aware that the existence of facilities to house laboratories and animals, and the availability of technicians to treat animals, do not, in and of themselves, assure meaningful toxicological evaluations. It is also necessary to have qualified and experienced toxicologists to supervise the testing process and to evaluate, present, and review the data.

In this regard, the current under-utilization of testing capacity may be beneficial to both industry and government in at least one respect. The dramatic growth in contract laboratories during the 1970's was not accompanied by a corresponding capability to conduct high-quality testing meeting the Good Laboratory Practices (GLP) requirements of agencies like EPA and FDA. However, the present underutilization of testing capacity allows industry and government sponsors to be more discriminating in their selection of contract laboratories. This selectivity, in turn, increases the likelihood that the resulting test data will be sufficiently reliable for industry and regulatory safety assessments.

● 2. Other testimony indicated that most new chemicals are minor modifications of existing chemicals, and that their effects can readily be predicted from what is already known about similar, closely related chemicals. But this is reassuring only to the extent that the similar chemicals have been well tested. And we heard testimony from a panel of scientists that there are huge areas where basic knowledge is lacking, even for chemicals that have been around for awhile.

● Do you believe that existing chemicals are well enough characterized that most new chemicals need little or no testing?

The need for testing new chemicals or existing chemicals should not be based solely on the presence or absence of toxicological data. The chemical and physical characteristics, the extent of potential exposures, and the characteristics of exposures must all be considered. For some classes of chemicals, there are adequate data bases, including data gained through actual use of the chemicals, to determine that a new chemical need not be tested.

In some instances, the physical and chemical properties of existing substances may serve as reliable indicators of the new chemical's potential toxicity. For example, most polymer systems are biologically inert; this provides significant assurance of low toxicity even in the absence of corroborative test data. It is therefore reasonable to presume that new polymers with similar chemical and physical properties will likewise have low toxicity. For such chemicals, testing would be an inappropriate use of limited resources, even if the potential for exposures was great.

For other classes of new chemicals, structural similarities plus some level of testing may be adequate to determine that the new chemical has a similar level of toxicity potential to an existing chemical. Thus, resources would be more appropriately devoted to engineering controls for minimal to no exposure than for extensive toxicity testing.

For still other classes of chemicals, the toxicity and exposure potentials are of such a magnitude that an unacceptable risk may occur under use or misuse conditions unless the level of control is known with a high degree of certainty; for these new chemicals, substantial testing must be conducted.

As the above discussion suggests, there are occasions when the results of testing on analogous existing substances may play a role in predicting the toxicity of new chemicals. However, not all new chemicals can be evaluated on the basis of toxicological information concerning existing substances. In some situations, either no existing chemical will be structurally similar to the new chemical or the data base on analogous compounds will be incomplete. In such situations, toxicity testing on the new substances may be necessary for a meaningful evaluation of its health or environmental effects. We believe that the PMN experience to date confirms that industry is in fact testing new chemicals when experience or data on analagous substances cannot supply the information necessary for sound safety assessment.

It is my judgment that sufficient test data and use experience are available on existing substances for structure-activity relationships to play a valuable role in screening new chemicals. While occasional gaps exist, the toxicological data base on most commercially significant compounds is relatively extensive. We are attaching a summary of the publicly reported data on the fifty largest volume chemicals produced in the United States. This summary confirms that mammalian toxicology and ecotoxicology properties are available for virtually all of these substances.

I believe that a similar conclusion would emerge from a survey of the available data for other large-volume substances with significant exposure potential. The extensive testing which has been performed on these chemicals is reflected in the large number of toxicity studies, totaling over 4,000, that were submitted to EPA in response to its recent rule under Section 8(d) of TSCA. Equally revealing are the deliberations of the Interagency Testing Committee (ITC), which is responsible for determining testing needs on existing chemicals. During the past two years, the ITC has dropped several dozen compounds from consideration because the data-bases that exist on these compounds are sufficient for a meaningful safety assessment.

Rohm and Haas's own activities are quite relevant in this regard. Since the mid-seventies, Rohm and Haas has supported chronic oncogenic studies on methyl methacrylate, methyl acrylate, ethyl acrylate, butyl acrylate, and numerous FIFRA-regulated materials. In addition, we are a charter member of the Chemical Industry Institute of Toxicology (CIIT), which has completed chronic evaluations of 8 materials and published over 700 scientific papers since 1976. Furthermore, many more research chemicals were tested as a part of routine testing or screening. We at Rohm and Haas have conducted one or more toxicity test on approximately 2,000 chemicals or mixtures over the last five years.

● 3. Dr. Davies testified that the chemical industry argued in the mid-70's that TSCA was unnecessary because firms already performed adequate testing, including testing of new chemicals. However, in general, little data are being submitted to EPA in PMN's.

● Does your company now do more or less testing of new chemicals as a result of TSCA? Has TSCA changed the incentive to conduct testing?

In general, Rohm and Haas does not do more or less testing of new chemicals as a result of TSCA. However, for some new chemicals, the timing of testing has been changed. In some cases, TSCA has caused an increase in the testing of existing chemicals.

For Rohm and Haas, the major impetus to toxicological testing of new and existing chemicals has come from advancements in toxicology and from an increased awareness of the potential some chemicals have to cause adverse health effects upon high exposure. These factors resulted in the development of in-house toxicological testing capabilities in 1973.

I cannot accept the premise underlying this question: that "in general, little data are being submitted to EPA in PMN's." The adequacy of the test data included in PMNs cannot be measured solely by numerical tabulations. Rather, it is necessary to determine whether or not EPA is receiving the information required to conduct meaningful health and environmental assessments of new chemicals, given their projected use and exposure conditions, their chemical and physical properties, and the toxicological information available for related substances. When these factors are considered, we believe that EPA is receiving the information it needs for a reasoned evaluation of most new chemicals.

In general, the PMN provisions of TSCA have reinforced the commitment of prudent manufacturers to test new chemicals where necessary for a sound assessment. Section 5(e) of TSCA contains important incentives for developing adequate information on new chemicals. Under this provision, where a PMN lacks sufficient data on a chemical's health or environmental effects, EPA can prohibit or limit the chemical's manufacture if it may present an unreasonable risk or will have substantial production volume and significant environmental release or human exposure. Thus, Section 5(e) encourages manufacturers to identify and develop the information that is needed for a reasoned evaluation of a new chemical's risks.

It is our impression that TSCA's PMN requirements have had the greatest impact on smaller chemical producers who have adopted formalized programs for health and environmental assessment in response to the law's provisions. Thus, these companies have primarily responded to PMN requirements by screening new substances more intensively, and conducting a more thorough evaluation of testing needs, in order to anticipate the EPA review process. Larger producers, by contrast, had generally established systematic review procedures for new chemicals before TSCA's enactment.

● 4. Dr. Gough of the Office of Technical Assessment testified that he was surprised how few PMN's included chronic health effects information. Asked why he thought so little testing was done, he said he didn't know, but that he doubted cost was a factor because a mutagenicity test, at least, is inexpensive.

● Are you surprised that so few new chemicals have been tested for mutagenicity? And why do you think industry has not been conducting such tests?

Chronic toxicity studies require four to six years to complete after the decision is made to initiate toxicological evaluations. These studies require some 30 to 60 man-years of effort to complete. In view of their length and expense, it should not be surprising that chronic toxicity studies are rarely submitted with PMNs.

Often there may be little need for chronic health effects testing at the premanufacture stage of a new chemical's development. During the initial period following PMN submission, many new chemicals are used in applications where the potentially exposed population is small, and exposure is both brief in duration and limited in concentration. Moreover, as EPA's experience confirms, a substantial number of PMN chemicals are never commercialized, while others are manufactured for short periods and then abandoned as commercial failures. For these reasons, a large number of PMN chemicals lack the potential for continuous, long-term human exposure which might necessitate chronic health effects testing. Many chemical manufacturers, therefore, defer consideration of such testing until new chemicals have demonstrated their commercial viability and long-term human exposure is a realistic possibility.

Another factor which influences the PMN submitter's level of surrounding chronic health effects testing is the new substance's chemical structure. Many new substances belong to chemical classes which are known to have little potential for biological activity. Polymers constitute one class of compounds for which little if any toxicity testing is normally necessary. On the other hand, some materials, such as highly reactive alkylating agents, may be assumed to be potentially highly toxic. Thus, prudent manufacturers will decide to devote resources to containment of the material by engineering practices instead of to toxicity testing.

Most of the 'inexpensive' in vitro mutagenic tests have been used primarily as screening mechanisms to detect the ability of a material to interact with DNA under artificial biological conditions. The data are then used to prioritize additional testing including testing for chronic health effects and to predict carcinogenicity. The success of these in vitro mutagenic test varies with the class of compound and from one investigator to another. Therefore, they are used with varying degrees of success in different situations and are inappropriate when applied across the board.

At Rohm and Haas, we use the Ames and other mutagenic test advisedly, depending upon the class of chemical under investigation and usefulness of the test, to provide insight into the potential hazard of a chemical.

When the above factors are taken into account, the amount of mutagenic testing conducted on new chemicals is satisfactory. According to OTA, over 25 percent of non-polymer PMN's have contained some mutagenicity data. This figure is reasonable in light of the large number of PMN substances that either have a low level of biological acitivity, lack the potential for long-term exposure, or cannot be reliably screened in mutagenicity assays.

● 5. There have been reports over the years about the possible adverse impact TSCA may have in terms of innovation of new chemicals. Has your company seen a large reduction in new chemical development as a result of TSCA? Are there many products your company would produce if TSCA didn't exist?

● Can you give any descriptive examples of safe and probably profitable chemicals that you did not attempt to manufacture as a direct result of the cost of filing a PMN?

Rohm and Haas has not experienced a reduction in new chemical development as a result of TSCA. However, we have become conservative in initiating new ventures as premarketing costs have increased and test marketing has decreased giving less assurance of the existence of a market.

As a manufacturer of large-volume chemicals, Rohm and Haas's experience with the PMN process may not be typical of the chemical industry as a whole. Many new chemicals are manufactured in small quantities and generate limited revenues early in their development. Therefore, the costs incurred by PMN requirements may often constitute a real barrier to innovation. Where a new chemical represents a minor improvement over existing materials, an increase in development costs will generally be reflected not in a higher price but in a reduced profit margin. Thus, if PMN costs are sufficiently high, the manufacturer's profits may disappear entirely. Under these conditions, there would no longer be an economic incentive to introduce the new substance and a rational manufacturer would abandon its development.

For the chemical industry as a whole, the available data do not permit a precise comparison of the overall level of new chemical introductions before and after TSCA's PMN requirements took effect. We believe, however, that the limited information which exists confirms that a real decline in innovation has in fact occurred.

● 6. I assume you are familiar with the array of toxicity tests known as "Minimum Premarket Data", or MPD, that was developed by the OECD. Let us assume that you had, for a particular chemical, good data from each type test listed in the MPD. Please rate as "good", "fair", "poor", or "not possible", the predictive ability of this set of data in terms of the potential for human toxicity for each of the following types: neurotoxicity, behavioral abnormalities, cancer, birth defects, gene defects, reproductive dysfunction, sublethal metabolic dysfunction, acute effects of various types.

● Please explain whether and how your company assesses explicitly the toxicity of a new chemical for each of these effects before it is marketed. Is there an official in you company who is required to sign off on the safety of a new chemical before it can be marketed?

The tests included in the OECD MPD may be useful in assessing the health and environmental effects of some new chemicals, but they will not be appropriate for all new substances. The selection of a suitable battery of tests for a new chemical is not a mechanical process. Informed professional judgment must be applied in light of several factors, including the toxicity profile of related chemicals, available test data on the new chemical and analogous compounds, the new substance's physical and chemical properties, the amount, route, and duration of the chemical's anticipated human exposure and environmental release, and the chemical's expected production volume and intended uses. An informed analysis of these factors may lead to the conclusion that some, all, or none of the tests specified by the MPD are appropriate for particular compounds.

The tests in the OECD MPD are rated in tabular form below for their predictive abilities to identify the potential of a new chemical for human neurotoxicity, behavioral abnormalities, cancer, birth defects, gene defects, reproductive dysfunction, sublethal metabolic dysfunction, and acute effects of various types. With the exception of acute and a few other selected effects, I have rated the predictive values of the OECD MPD as "poor." I have also assigned a "fair" or "good" rating to structure-activity relationships.

TEST	EFFECTS							
	neuro	behav.	cancer	birth	gene	reprod	sublethal	acute
Structure	F-G	F-G	F-G	F-G	F-G	F-G	F-G	F
Oral	P-F	P-F	P	P	P	P	P-F	F-G
Dermal	P-F	P-F	P	P	P	P	P-F	F-G
Inhalation	P-F	P-F	P	P	P	P	P-F	F-G
Eye/Skin	P	P	P	P	P	P	P	F-G
Sensitiz.	P	P	P	P	P	P	P	F-G
Repeat	P-G	P-G	P	P	P	P-F	P-F	P-F
Mutagen.	P	P	P-F	P	P-G	P	P	P

F = Fair; G = Good; P = Poor

It should be stressed that the few ratings of "fair" in the above table are not dependent upon the test per se, but upon the evaluation of the test results by highly trained and experienced toxicologists. Where a rating of "good" has been indicated, the rating would be limited to a relatively few chemical classes evaluated by a limited number of highly skilled toxicologists.

On the surface, the above table suggests that to protect humans, a full battery of toxicity tests must be conducted on all new chemicals. However, for most new chemicals, such a comprehensive testing is neither necessary for safe use and handling nor resource-efficient. To appreciate this, one must first be aware that the risk or probability of an adverse health effect is dependent on the hazardous potential of a chemical on the potential for exposure. There will be little to no risk of potential adverse health effects if exposure potential is low. Similarly, if hazard potential is low, there will be little or no risk even if exposure potential is great. It is this principle that dictates the proper risk assessment program for each new chemical. As no two chemicals have the exact same hazard potential and exposure patterns, each risk assessment program must be considered separately.

Rohm and Haas assesses the health and environmental effects of new chemicals by addressing the following questions:

1. What is the proposed use for the new chemical?

2. What are the potential exposures to the new chemical?

3. What are the intrinsic toxic properties of structurally related chemicals?

If the proposed use and potential exposure are limited to accidental exposures to a limited number of workers, an acute toxicity profile will be considered.

If the proposed use and potential exposure suggest possible repeat exposures to workers, customers, and/or consumers, repeated exposure tests are considered. Those tests will evaluate the absorption, distribution, metabolism, and excretion of the chemical, as well as the potential for the chemical to produce tissue damage, neurotoxicity, behavioral abnormalities, birth defects, gene defects, reproductive dysfunction, and sublethal metabolic dysfunction. The specific test design is tailored to the chemicals based on structure-activity relationship studies and exposure potential.

If the proposed use and potential exposure suggest a significant possibility of chronic exposures of workers, customers, and/or consumers, chronic and carcinogenic tests are added to the battery of tests conducted under the previous two conditions.

When appropriate, reducing the potential exposure to the chemical is preferred to toxicity testing. In all assessments, the above procedures are used only as guidelines. As information becomes available, the program will be upgraded or downgraded as appropriate.

At Rohm and Haas, each new chemical (product) after evaluation by the Toxicology Department, must be approved by the business group responsible for the product, the Product Integrity Department which has responsibility for compliances with state and federal product regulations as well as hazardous information and communications (Material Safety Data Sheets [MSDS]), and the Corporate Health Safety and Environmental Affairs Department which has responsibility for our workers and compliance with environmental regulations.

(s) Jerry M. Smith, Ph.D., D.A.B.T.

Jerry M. Smith, Ph.D., D.A.B.T.
November 9, 1983

SUMMARY OF DATA AVAILABLE AND TESTING PLANNED ON U.S. "TOP 50" CHEMICALS

	Data Available*				
Chemical Substance	Physical Properties	Human Health Mammalian Toxicology	Ecotoxicology	Testing Planned or Underway	Scored by ITC (R=Recommended
Acetic Acid	X	X	X		
Acetic Anhydride	X	X	X		
Acetone	X	X	X	X	
Acrylonitrile	X	X	X	X	
Adipic Acid	X	X	X		
Aluminum Sulfate	X	X	X		
Ammonia	X	X	X	X	
Ammonium Nitrate	X		X		
Ammonium Sulfate	X	X			
Benzene	X	X	X	X	
1,3-Butadiene	X	X	X		X
Calcium Chloride	X	X	X		
Calcium Oxide	X	X	X		
Carbon Black	X	X	X		X
Carbon Dioxide	X	X			
Chlorine	X	X	X	X	
Cumene	X	X	X		X
Cyclohexane	X	X	X		X
1,2-Dichloroethane	X	X	X	X	X
Ethanol	X	X	X		
Ethyl Benzene	X	X	X		X
Ethylene	X		X	X	X
Ethylene Glycol	X	X	X	X	X
Ethylene Oxide	X	X	X	X	R
Formaldehyde	X	X	X	X	X
Hydrochloric Acid	X	X	X		
Methanol	X	X	X	X	
Nitric Acid	X	X	X		
Nitrogen	X				
Oxygen	X				
Phenol	X	X	X	X	
Phosphoric Acid	X	X	X		
Propanol	X	X	X		
Propylene	X		X		X
Propylene Oxide	X	X	X	X	R
Sodium Carbonate	X	X			
Sodium Hydroxide	X	X	X		
Sodium Sulfate	X	X	X		
Sodium Tripolyphosphate	X	X	X		
Styrene	X	X	X	X	X
Sulfuric Acid	X	X			
Terephthalic Acid	X	X		X	X
Titanium Oxide	X	X	X	X	X
Toluene	X	X	X		R
Urea	X	X	X	X	
Vinyl Acetate	X	X	X	X	
Vinyl Chloride	X	X	X	X	
Water Glass	X	X			
p-Xylene	X	X	X	X	R
Xylene	X	X	X	X	X

*Results of preliminary searches. It is not exhaustive and does not reflect proprietary data.

Natural Resources Defense Council, Inc.

122 EAST 42ND STREET
NEW YORK, N.Y. 10168
212 949-0049

Washington Office
1725 I STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20006
202 223-8210

Western Office
25 KEARNY STREET
SAN FRANCISCO, CALIF. 94108
415 421-6561

TESTIMONY OF
JACQUELINE M. WARREN
NATURAL RESOURCES DEFENSE COUNCIL
BEFORE THE
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT
OF THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

August 1, 1983

New England Office: 17 ERIE DRIVE • NATICK, MA. 01760 • 617 655-2656
Public Lands Institute: 1720 RACE STREET • DENVER, CO. 80206 • 303 377-9740

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Introduction

The Natural Resources Defense Council (NRDC) is a national non-profit environmental organization supported by 40,000 members and contributors who are dedicated to the wise use of the nation's land and water resources, and to the protection of human health and the environment. Since its inception in 1970, NRDC staff attorneys and scientists have been involved in administrative, legal and legislative efforts to control involuntary exposures to toxic and especially cancer-causing substances in the environment. NRDC has monitored the EPA's implementation of the Toxic Substances Control Act (TSCA) since its passage in 1976. We welcome this Subcommittee's oversight of EPA, and appreciate this opportunity to present our views on the Agency's overall performance in implementing the Act.

TSCA was passed in response to repeated disclosures about the severe adverse health, environmental and economic damage inflicted by such widely used substances as asbestos, PCBs, kepone, vinyl chloride, and PBBs, to name but a few. The Act was intended to remedy the lack of legal authority either to prevent such problems from arising, or to deal adequately with them after the fact of injury or serious risk was established.

The clearly-stated overriding purpose of TSCA is to prevent unreasonable risks of injury to health and the environment resulting from exposure to toxic substances. The basic objectives of the law, as set forth in §2, are that adequate data on the effects of chemicals should be developed by those who produce them; that EPA should have adequate authority to regulate chemical substances which present an unreasonable risk of injury to health and the environment; and that undue or unnecessary burdens on commerce and innovation should be avoided in "fulfilling the primary purpose of the Act to assure that such innovation and commerce in chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." (TSCA §2(c)(emphasis added)).

To achieve these purposes, Congress provided EPA the authority to screen new chemicals to identify potential "bad actors" before, rather than long after, their entry into commerce; to require that existing or new chemicals be tested to determine whether they are hazardous; to restrict or even prohibit their manufacture and use in appropriate circumstances; and to gather from the chemical industry and elsewhere the information necessary to support regulatory decisions. Extensive opportunities for public input, involvement and oversight were also included in the statutory framework in recognition of the public's right to know the basis of decisions concerning the effects of toxic substances on health and the environment.

In each of the aforementioned areas of statutory authority and responsibility, a clear pattern of implementation has emerged at EPA over the past several years. It is a pattern that deemphasizes the primary purpose of TSCA, which is protection of health and the environment, in favor of avoidance or elimination of those TSCA requirements, both statutory and administrative, that the chemical industry deems burdensome. The result has been the transformation of TSCA into a largely voluntary program for the testing, screening and control of toxic substances.

Examples of the voluntary approach are readily apparent. Where the statute requires premanufacture screening of all new chemicals by EPA, the Agency instead is proposing broad exemptions covering 50% or more of them. Where the statute calls for the issuance of rules to govern the testing of suspect chemicals identified by an expert inter-agency committee as the highest priority candidates for testing, EPA instead is negotiating voluntary and unenforceable testing programs which minimize public participation in their development, and which frustrate several other statutory provisions triggered by §4 test rules. Moreover, the data submitted to EPA by manufacturers of new chemicals are frequently so insufficient or nonexistent regarding the toxicity of the chemicals that EPA is reduced to making educated guesses about their potential health and environmental effects.

Finally, where the statute directs EPA to act to control existing chemical hazards, the Agency has announced that it will do so only as a last resort, preferring voluntary control measures instead. Thus, EPA is construing its authority under

TSCA in the narrowest possible terms, even though the courts have traditionally held that statutes designed to protect public health should be broadly interpreted in order to achieve their preventive or remedial purposes.[1]

This assessment of EPA's performance is not made lightly. Despite repeated comments, suggestions and criticisms of EPA by members of Congress, the EPA Administrator's Toxic Substances Advisory Committee, and organizations such as NRDC, it is clear that the mandate and the promise of TSCA are not being fulfilled. The particular areas of concern that NRDC believes warrant attention by this Subcommittee are the following:

1. Testing of New Chemicals

The premanufacture notification provisions of §5 of TSCA have been called "the heart of the Act."[2] As stated above, the purpose of premanufacture notification is to identify potentially hazardous new chemicals before rather than long after their entry into commerce. As the Conference Report on TSCA clearly states:

> The provisions of the section reflect the conferees' recognition that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects occurs before commercial production begins. Not only is human and

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[1] See, e.g., EDF v. EPA, 598 F.2d 62 (1978), and cases cited therein.

[2] Legislative History of the Toxic Substances Control Act, House Committee on Interstate and Foreign Commerce, 722 (1976)(Remarks of Sen. Magnuson).

> environmental harm avoided or alleviated but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. (H. Rep. No. 94-1679, 94th Cong., 2d Sess. 65 (1976)).

In order to carry out its statutory responsibility to evaluate the potential health and environmental effects of a new chemical, EPA must necessarily have a certain amount of toxicity data about the substance. As presently written, however, TSCA does not require PMN submitters to generate and submit any toxicity data at all on the new chemical. Only if a manufacturer voluntarily undertakes to generate toxicity data, and has it available at the time a PMN is submitted, does TSCA require that the data be submitted. As a result of this shortcoming in the law, almost 50% of the PMNs submitted since the program began in 1976 have come in to EPA with no toxicity data whatever.[1]

EPA has authority under §5(e) of TSCA to reject PMNs that lack toxicity data, on the grounds that the available information "is insufficient to permit a reasoned evaluation of the health and environmental effects" of the PMN chemical. This procedure requires EPA to go to court on a case-by-case basis, however, and has been infrequently utilized. Instead, the Agency has assumed the burden of assessing potential hazards without data regarding the specific new chemical being evaluated.

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[1] The Information Content of Premanufacture Notices, U.S. Congress, Office of Technology Assessment 6 (1983).

To accomplish this feat, the Agency must rely almost entirely on information concerning structure-activity relationships (SAR), i.e., EPA assesses the potential risks of new chemicals by studying available information on similar chemicals. In most cases, the Agency has very little or no data on the toxicity of the PMN chemical itself.

While SAR information can be helpful in alerting the Agency about the known toxicity of chemicals that are structurally similar to the PMN chemical, it is not a substitute for toxicity data about the PMN chemical itself. The inadequacies of reliance upon structure-activity analyses for regulatory decision-making have been underscored by several scientific organizations. For example, the American Chemical Society has criticized EPA's proposed reliance upon SAR analysis for PMN exemptions:[1]

> Although it is a useful technique with predictive capabilities, structure-activity analysis is still evolving. The technique has been neither fine-tuned enough nor sufficiently peer-reviewed and accepted by the scientific community at large to be used as the primary basis for regulatory decision-making.

Similarly, the European Environmental Bureau has commented that "structure-activity analysis, in its still primitive state of development regarding toxicological and eco-toxicological effects, is not an adequate substitute for testing information."[2]

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[1] Letter from Robert W. Parry, American Chemical Society, to Anne M. Gorsuch, Administrator, Environmental Protection Agency, October 4, 198 Re: Exemptions from Premanufacture Review.

[2] Comments of the European Environmental Bureau on EPA's proposed Exemptions from Premanufacture Notification, September 30, 1982.

On January 27, 1981, EPA published as a policy statement a recommended approach to premanufacture testing that endorsed and suggested that domestic chemical producers develop the Minimum Premarket Data Set now provisionally agreed upon by all but one (the United States) of the 24 member countries of the Organization for Economic Cooperation and Development (OECD) as an appropriate starting point for the prediction of risk of new chemicals. The OECD Premarket Data Set is almost identical to the premarket testing scheme adopted and currently being implemented by the member countries of the European Common Market. Such a testing scheme is not a requirement in the United States, however. Moreover, the American chemical industry has so far successfully opposed endorsement by the United States of the OECD Minimum Premarket Data Set. To the extent that chemical producers in the United States are required to do far less than their European counterparts to generate data on the health and environmental effects of their new chemicals, the American public is the loser.

In NRDC's view, the existing PMN program is not accomplishing the Congressional objective. Over the past three years, EPA has received more than 2,300 PMN notices. Recent Agency figures and the OTA Report show that almost half of the notices were submitted with no data whatever on the toxicity of the new chemical. Only 14% contained mutagenicity data and less than 10% included environmental fate information. The most frequently submitted information, showing acute oral toxicity, was included in less than 35% of the notices. These statistics suggest that the PMN program as currently implemented is not encouraging the voluntary development of premanufacture health and environmental effects data, not even the most basic acute toxicity data. On the contrary, it appears that many of the largest chemical producers, who can best afford to test their products prior to marketing, are not routinely doing so.

Under the existing system, many new chemicals enter commerce, where they may greatly increase in volume and exposure, although they remain untested and uncharacterized for adverse health and environmental effects. Without actual data on those new chemicals at the PMN review stage, EPA can only utilize inadequate SAR analyses and make what are at bottom only guesses about their future health and environmental impacts. Moreover, although EPA could do so, it has not established a system to track the new chemicals once they enter commerce, and to require additional information as volume and use patterns grow. The few significant new use rules and §8(a) reporting requirements recently proposed by EPA in no way reduce the urgent need for such a tracking system.

The legislative history of TSCA strongly suggests that Congress intended in §5 to put an end to the "use first, test later" approach to chemicals manufacture that had given us PCBs, vinyl chloride, PBBs and a litany of other notorious chemicals. Seven years later, it is clear that we are still allowing most new chemicals to enter commerce with little or no toxicity testing. It is also clear that the chemical industry's frequent claim that testing requirements are not needed because new chemicals are being tested, is simply not true. Rather than voluntarily testing their new chemicals to identify "bad actors" prior to commercialization, the chemical industry in the United States appears to be conducting business as usual, and continuing to use the workplace, the general public and the environment as a testing laboratory for determining the adverse effects of their products.

We believe that Congress should act now to stimulate innovation in safer chemicals and to deter innovation in hazardous chemicals. This result can be accomplished by amending TSCA to authorize and require pre-market testing of new chemicals so that chemical producers selling in the United States will have to do at least as much to anticipate the adverse health and environmental effects of their chemicals as they are required to do before entering the European market.

2. PMN Exemptions

Instead of focusing on ways to stimulate the chemical industry to develop more toxicity data on new chemicals, EPA is in the final stages of promulgating sweeping exemptions from the PMN requirements of §5 of TSCA. Responding to a petition by the Chemical Manufacturers Association (CMA), EPA proposed and received comment upon a scheme that could exempt 50 percent or more of new chemicals from full PMN review. According to the proposal, the exemptions would be for new chemicals produced in volumes under 22,000 pounds a year, for new chemicals produced and consumed at the site of manufacture, regardless of volume, and for new polymers. Although a small number of new chemicals exhibiting certain very toxic effects would not be eligible for exemption, new chemicals would generally be exempted if a "qualified expert" employed by the producer certifies to EPA that the chemical is eligible.

Section 5(h)(4) of TSCA provides for exemptions from all or part of the PMN requirements "upon application and by rule," contingent upon a finding by the Administrator that there will be no resulting unreasonable risk. We are concerned that a proposal that would exempt half of all new chemicals from premanufacture screening, by means of broad exemption categories, is incompatible with Congress' intent that the Administrator make a definitive finding of no unreasonable risk. In our view, the combination of broad PMN exemptions and extensive toxicity data deficiencies in the PMN notices for new chemicals that would continue to be subject to the PMN requirements would effectively defeat the original purpose of premanufacture notification.

3. Voluntary Testing of Suspect Chemicals

Section 4 of TSCA requires EPA either to propose rules to require testing or to decide that testing is not necessary for selected existing suspect chemicals designated as high priority for testing by a committee of experts, the Interagency Testing Committee (ITC), within one year of such designation. Chemicals recommended by the ITC are selected because they are produced and used in very large quantities and have exposure potential and biological or chemical properties that are likely to pose risks of cancer, gene mutations, birth defects, or environmental damage. When EPA failed to act on the first recommended priority chemicals within the statutory period, NRDC brought suit. In February 1980, a United States District Court ruled that EPA was required to act within 12 months after receiving the ITC's recommendations, and in January 1981, placed EPA on an expedited schedule for action on the listed priority chemicals.[1] According to the schedule, EPA was ordered to propose test rules or decide that testing is unnecessary for 11 priority chemicals in 1981, 13, in 1982, and 13 in 1983.

Although in affidavits to the court, various EPA officials have represented that the deadlines are being met, observation of the Agency's actions suggests that compliance is in form rather than in substance. Almost three years have passed since the proposal of the first testing rules for three chemicals on the list, and more than one year since a second proposal for three more chemicals, but no final testing rules have ever been issued. Indeed, in the seven years since passage of TSCA EPA has failed to issue a single testing rule. Instead, the Agency's policy is to engage in negotiations with manufacturers of the chemicals earmarked by the ITC as the highest priorities for testing, in order to stimulate the development of voluntary testing programs for the chemicals in lieu of binding and enforceable testing rules under §4.

NRDC recognizes that voluntary testing by the manufacturers of chemicals is an objective of TSCA, and we would welcome the widespread acceptance of this responsibility by the chemical industry. Voluntary testing schemes for the priority chemicals recommended by the Interagency Testing Committee, however, raise issues that voluntary testing of other chemicals does not. The priority chemicals are those suspected by an expert committee of posing potential hazards to health and the environment, and for which specific toxicity tests, especially for carcinogenicity, mutagenicity and teratogenicity, have been recommended. They are covered by one of the few action-forcing provisions of TSCA, §4(e), and EPA's decisions to issue test rules trigger numerous other statutory requirements. For example, development of test rules involves extensive public input (notice-and-comment rulemaking), Federal Register notice and public access to data produced pursuant to a testing rule (§§4(e) and 14(b)), submission of test data with a PMN (§5(b)); enforceable laboratory procedures and testing deadlines (§15); and notification to foreign governments of the export of a substance subject to a test rule (§12).

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[1] NRDC v. Costle, 14 ERC 1858,____ F.Supp._____ (S.D.N.Y. 1980).

EPA contends that negotiated testing agreements will accomplish the objectives of §4(e) faster and better than would testing rules. We disagree. Acceptance by EPA of voluntary testing schemes developed by industry as a substitute for the notice and comment rulemaking provided by TSCA is resulting in industry testing commitments that are not enforceable, may not be adequately comprehensive, may never be completed, and which are developed with little, if any, public oversight and involvement. EPA's recent problems with the voluntary agreement for testing chlorinated paraffins dramatically illustrates the validity of these concerns. The Chlorinated Paraffins Consortium, an international group of paraffins producers whose voluntary testing scheme was the first one accepted by EPA, has refused to provide raw testing data the Agency requested. Moreover, the Consortium has changed the agreed-upon testing program without notifying EPA, and will be two years late in completing certain segments of the program.[1] EPA cannot enforce the original "agreement" except by incorporating it at this late date into a §4(a) testing rule.

EPA could anticipate such problems and correct the other legal deficiencies described above by supplementing the voluntary programs with rules incorporating the agreed-upon protocols and specifying necessary additional testing and use of validated protocols, by imposing enforceable deadlines for completion of the tests, and by involving the public to the same extent as §4 provides.

EPA can only guarantee that the chemicals recommended by the ITC for priority testing will actually be properly and expeditiously tested if the procedures specified by Congress in §4(a) are followed. Section 4(e) would not have been enacted as an action-forcing provision if voluntary testing--or not--depending upon the whim or good faith of the manufacturer, were an acceptable alternative. We urge the Subcommittee to consider carefully the implications of EPA's current interpretation of what §4(e) requires with respect to testing of the ITC chemicals, and to reaffirm the original intent of the section through oversight or specific legislative language.

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[1] Chemical Regulation Reporter, July 1, 1983, pp.467-8.

4. Adequacy of EPA's Implementation of §6

Section 6 is the principal regulatory provision of TSCA. It provides EPA with broad powers to control exposures to toxic substances, including imposition of warnings and notices, geographic or poundage limitations on manufacture, restrictions on use, or outright prohibitions. The authority reaches every aspect of chemical production, from manufacture to processing, distribution in commerce, use and disposal.

Since TSCA was passed in 1976, EPA has exercised its §6 authority only a few times. During the Carter Administration, §6 was invoked to prohibit the use of non-aerosol chlorofluorocarbons, to prevent the burial of dioxin-contaminated waste at a manufacturing site in Arkansas, and to implement Congressionally-mandated requirements for marking and disposal of PCBs as well as a phase-out of manufacture and open system uses of PCBs.

The Reagan Administration's principal activities under §6 are not much more impressive. For example, the Agency has determined that formaldehyde is not of sufficient health concern to warrant regulatory consideration. (Although this action technically arose under §4(f), that section was designed to channel hazardous chemicals into the regulatory provisions of TSCA §§5, 6, and 7). EPA has also issued watered down requirements for the inspection of deteriorating asbestos structural components in public schools, a Carter administration initiative that was promulgated only after heavy Congressional pressure was brought to bear on the Agency. In addition, pursuant to a court-ordered schedule, EPA has re-written the PCB ban regulations overturned in 1980 by the D.C.Circuit. Finally, an Advance Notice of Proposed Rulemaking regarding possible regulation of 4,4'-methylene bis (2-chloroaniline)(MBOCA), a carcinogenic hardening agent used in the manufacture of polyurethane plastics, has been published. No other §6 regulatory actions are presently proposed or otherwise pending.

a) Formaldehyde

Concerns about EPA's will to act against potentially hazardous substances were raised by the Agency's February 1982 determination that the risks posed by continuing exposure of the population to formaldehyde are "insignificant" and do not warrant any investigation of possible regulatory options. Formaldehyde has been shown to be carcinogenic in laboratory animals and is very widely used in the United States.

NRDC believes that EPA's decision not to consider formaldehyde further as a candidate for regulatory action violates §4(f) of TSCA, which provides that:

> Upon receipt of (1) any test data required to be submitted under this Act, or (2) any other information available to the Administrator, which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations or birth defects, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under §§5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable....

In the spring of 1981, the staff of the Office of Pesticides and Toxic Substances recommended that formaldehyde and di(2-ethylhexyl) phthalate (DEHP), another carcinogenic and widely-used chemical, be designated for priority evaluation under §4(f). Subsequent to receiving these recommendations, the former Deputy Administrator of EPA held a series of secret "science courts", principally involving industry representatives, on both chemicals. The propriety of conducting such "science courts", and the validity of the criteria used by EPA to assess the carcinogenicity of formaldehyde, were the subjects of a number of Congressional hearings, one as recently as March 1983 by a House Subcommittee. NRDC is currently seeking judicial review of the manner in which EPA reached its decision not to consider formaldehyde as a candidate for regulatory action.

Perhaps the most troublesome aspect of the Agency's decision on formaldehyde is its reversal of ten years of EPA and federal regulatory policy on assessing the risks of carcinogenic substances. Even before EPA's decision was formally announced, concern about its implications prompted Dr. Arthur Upton, Director of New York University's Institute of Environmental Medicine and former director of the National Cancer Institute, to write to the regulatory agencies involved that formaldehyde "is decisively carcinogenic in animals.... If the carcinogenicity of formaldehyde is ignored, it would mean that no agent could be regarded as carcinogenic in the absence of positive evidence in humans."[1] At a later date, Dr. Upton again wrote to the heads of OSHA, EPA, and the CPSC to express his continuing concern that those agencies

> may be planning not to take immediate protective action on formaldehyde, in spite of substantial evidence for its carcinogenicity from animal bioassays. We are concerned about the possibility of such a departure from established public health policy. It would conflict with the prevailing views of the scientific community and would set a precedent which could hamper future regulatory action on other carcinogens.[2]

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[1] Letter from Dr. Arthur C. Upton to heads of federal regulatory agencies, August 17, 1981.

[2] Letter from Drs. Arthur C. Upton and I.B.Weinstein, January 29, 1982.

The Agency's inaction with respect to formaldehyde indicates that the Office of Toxic Substances is making regulatory decisions in both the toxics and pesticides programs,[1] that run directly contrary to "the prevailing views of the scientific community," although they are quite consistent with positions advanced by the Formaldehyde Institute and other industry representatives in their efforts to forestall or prevent regulation of carcinogenic chemicals.

EPA's drastic reversal of federal policy on carcinogens has been subject to intense scrutiny by Congress, by the broader scientific community and by the public. We are hopeful that under the leadership of the new Administrator, Agency staff will refrain from any further back-room meetings with industry scientists and lawyers, and will once again openly seek input from all points of view, especially on such a crucial public health question as the principles for determining the risks of exposure to carcinogens.

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[1] See EPA Pesticide Regulatory Program Study, Subcommittee on Department Operations, Research and Foreign Agriculture, House Committee on Agriculture, 97th Cong., 2nd Sess. (Dec. 17, 1982).

b) PCBs

The only toxic substances Congress specifically directed EPA to address were PCBs, for which deadlines were set for publication of marking and disposal requirements, and for imposition of prohibitions on use, manufacture, processing, and distribution in commerce, with limited exceptions.

EPA's record with respect to implementing the ban on PCBs bears particular mention because it well illustrates the Agency's continuing reluctance to impose requirements that would effectively control existing chemical hazards. PCBs are a family of extremely toxic, persistent industrial chemicals which have been widely used all over the world. They are present in human mother's milk and adipose tissue at toxicologically significant concentrations, and have caused severe economic damage and hardship, such as the closing of several rivers to commercial fishing because of high contamination levels.

At the present time, there are estimated to be more than 700,000,000 pounds of PCBs in use in electrical transformers, capacitors and other equipment. In 1979, EPA's approach to implementing the Congressional directive to ban PCBs, with limited exceptions, was to exclude 99.3% of the PCBs then in current use, from the prohibition. Nor did the Agency even require any inspection or monitoring for leaks. In response to a legal challenge to the adequacy of these "ban" regulations by the Environmental

Defense Fund (EDF), the United States Court of Appeals remanded the PCB ban regulations to EPA stating that they could "hardly be viewed as a bold step forward in the battle against life-threatening chemicals."[1] Pursuant to a judicially-ordered schedule to re-do the PCB ban regulations in a manner consistent with the Congressional mandate embodied in §6(e) of TSCA, the Agency issued re-written electrical equipment rules last August. Because of the breadth of the exceptions from the ban that EPA is still allowing for electrical equipment, NRDC and EDF have challenged the regulations again, as have various industry parties for other reasons.

On a more positive note, environmentalists and representatives of the Chemical Manufacturers Association recently submitted to EPA a joint proposal for a mutually acceptable re-write of the rule covering inadvertent manufacture of PCBs, which is also subject to the schedule established by the D.C. Circuit's order in EDF v. EPA.

Perhaps the most serious remaining problem involving PCBs arises from the fact that PCB disposal is governed by TSCA rather than by the Resource Conservation and Recovery Act (RCRA). Since no one is deliberately manufacturing commercial grade PCBs in the United States today, our major PCB problem is ensuring proper disposal of hundreds of millions of pounds of high concentration PCB transformer fluids and capacitors.

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[1] Environmental Defense Fund v. Environmental Protection Agency, No. 79-1580 (D.C. Cir., Oct. 30, 1980), p. 41.

Unfortunately, existing EPA requirements permit PCB "disposal" without manifests, at un-permitted storage facilities or un-inspected PCB landfills, through processes which may not be licensed by EPA, and the details of which are hidden from public view by a cloak of confidentiality.

It is imperative that this problem be addressed and that EPA be directed to act expeditiously to parallel in all relevant respects the manifesting, licensing, reporting, and facility operation requirements that apply to other disposal of hazardous waste under RCRA. In particular, the requirements governing PCB "storage for re-use" must be narrowed and strengthened to eliminate this category as an essentially unregulated avenue of PCB disposal. PCB contamination of the environment, and continuing uncontrolled exposures of the population to PCBs are certain to continue unless these problems are remedied as rapidly as possible.

c) "Voluntary" Regulation of Problem Chemicals

Instead of establishing a systematic program for identifying and controlling existing chemical hazards, EPA appears to be developing a "voluntary risk management advisory" approach whereby companies faced with potential §6 control actions would agree to develop voluntary controls on the chemical involved. Such an approach is under consideration, for example, to reduce the risk of skin cancer from waste motor oils, and has been suggested for control of the highly carcinogenic vapors emitted by unleaded gasoline. In NRDC's view, the entire statutory scheme of TSCA would be defeated by the adoption of exclusively voluntary approaches to implementation of what is inherently a regulatory statute.

As in the case of voluntary testing agreements instead of testing rules under §4, voluntary controls under §6 would effectively write out of TSCA the public involvement in decision-making guaranteed by the rulemaking provisions of §6(c), the effective date requirements of §6(d), the authority to gather information from small manufacturers under §8(a)(3), requirements for export notification under §12, the authority to impose import restrictions under §13, the mandatory compliance requirements of §15, the authority to impose civil and criminal penalties for non-compliance under §16, the specific enforcement and seizure requirements of §17, judicial review under §19, citizen enforcement under §20, citizens' petitions under §21, and employment effects studies and hearing rights under §24. In sum, adoption of voluntary approaches in lieu of rules under §§4 and 6 will destroy the statutory framework by rendering inoperative all of the statutory sections that depend upon the issuance of rules by EPA to implement the law. We would prefer that Congress repeal TSCA directly than permit such a systematic evisceration of its key authorities.

d) The Need for Specific Deadlines for Identification and Control of Existing Chemical Hazards

NRDC believes there is a pressing need for a change in TSCA that will give more specific direction to EPA's §6 program. The Agency now has unlimited discretion regarding which chemicals to address as candidates for regulation, and what schedule to follow in doing so. The result has been years of virtual inaction.

To remedy this deficiency in the TSCA program, NRDC suggests that TSCA be amended to establish a regulatory track for problem chemicals. This could be accomplished by enlarging the mandate of the expert interagency committee created under §4(e) to include recommending chemical candidates for regulation by EPA, which the Agency would have to consider within a set statutory period, such as 18 months. A similar requirement could and should be established where positive results are produced by testing mandated under §4. Until Congress acts to compel EPA to exercise its discretion to control toxic substances posing unreasonable risks to health or the environment, it is likely that the bureaucratic inertia at EPA will continue with respect to existing chemical hazards.

5. Impact of Confidentiality Claims on Access to Information

Despite the provision of §14(b) that health and safety data about chemicals cannot be withheld from disclosure on grounds of confidentiality, TSCA allows chemical manufacturers, processors and others covered by the statute to invoke broad confidentiality claims. Unlike other environmental statutes, such as the Clean Air Act and the Clean Water Act, which require public disclosure of environmental releases of toxic substances, TSCA permits such releases to be withheld on grounds of confidentiality.

The obstacles to public participation created by unduly broad confidentiality claims are well illustrated by certain Federal Register notices of a few months ago announcing receipt by EPA of PMN submissions, as required by §5(d)(2) of TSCA, for the ostensible purpose of facilitating public comment within the 90-day notice review period. The notices, which are appended as Attachment I, show that the submitting manufacturers claimed confidential their company names, the identity of the new chemicals, the proposed uses and estimates of production volume, the expected exposures, the expected environmental releases, and the anticipated methods of disposal. To add insult to injury, no data on toxicity were submitted.

What public purpose does such a notice serve? It is a waste of Federal Register space as well as the time spent by Agency personnel to prepare the notices. Most troubling of all is the complete exclusion of any possibility of public comment on the toxicity or proposed use of the new chemicals.

Is this what Congress intended when TSCA was enacted? Certainly, the allowable breadth of confidentiality protection under TSCA goes far beyond other environmental statutes in this regard. As a result, confidentiality has been claimed for 74% of the identities of all PMN chemicals, for PCB capacitor disposal processes, even for the amount of a fine levied by EPA for violation of the statute. Recently, a notice submitted under §8(e) of TSCA, which requires "immediate" notification to EPA of substantial health risks, described a potentially serious bone cancer hazard, but claimed both the chemical and company names confidential. In our view, information bearing on such potentially serious health hazards should be made public as a matter of course. Clearly, Congress so intended when it provided in §14(b) that "health and safety studies", broadly defined, were not to be withheld from public disclosure on grounds of confidentiality.

NRDC believes that the confidentiality protection available under TSCA should be narrowed to encompass only matters of genuine trade secrecy concern, such as product formulas. As currently written and administered, the confidentiality provisions of TSCA permit important health risk information and activities that may endanger health and the environment to be hidden from public view, and also effectively preclude public involvement in and oversight of the PMN review process.

Conclusion

TSCA was enacted in 1976 in response to strong public demand for basic changes in the way chemicals are developed and introduced so that the potential kepones and PCBs of the future could be identified in the laboratory rather than in medical records or in monetary losses caused by contamination incidents. Congress' intention that EPA use TSCA to begin to remedy such problems has not yet been carried out, and the problems caused by toxic substances are still very much with us.

Every public opinion poll taken in the last few years has confirmed that the American people want and strongly support strengthened efforts to protect health and the environment, especially in the area of toxic substances control. We welcome this Subcommittee's oversight and attention to the TSCA implementation problems described in this statement. Furthermore, we urge the members to consider amendments to TSCA that would (1) authorize EPA to require submission of the data it needs to evaluate new chemicals; (2) compel EPA to identify and address existing chemical hazards on a schedule commensurate with the urgency of the risks they may pose; (3) close the PCB disposal loophole; and (4) narrow the scope of confidentiality protection afforded by §14.

ATTACHMENT I

Dated: March 22, 1983.

Paul C. Cahill,

Director, Office of Federal Activities.

[FR Doc. 83-7710 Filed 3-24-83; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-59120; ISH-FRL 2330-2]

Certain Chemicals; Premanufacture Exemption Applications

AGENCY: Environmental protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA may upon application exempt any person from the premanufacturing notification requirements of section 5 (a) or (b) of the Toxic Substances Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which must either be approved or denied within 45 days of receipt, are discussed in EPA's revised statement of interim policy published in the Federal Register of November 7, 1980 (45 FR 74378). This notice, issued under section 5(h)(6) of TSCA, announces receipt of three applications for exemptions, provides a summary, and requests comments on the appropriateness of granting each of the exemptions.

DATE: Written comments by April 11, 1983.

ADDRESS: Written comments, identified by the document control number "(OPTS-59120)" and the specific time number should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Management Support Division, Environmental Protection Agency, Rm. E-401, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Theodore Jones, Acting Chief, notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-216, 401 M Street, SW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the submission provided by the manufacturer on the TME received by EPA. The complete non-confidential document is available in the Public Reading Room E-107.

TME 83-31

Manufacturer. Confidential.

Chemical. (G) Substituted Acetamide.

Use/Production. (G) Incorporated as a minor constituent in an article for use in commercial establishments. Prod. range: 3 month up to 0.2 kg

Toxicity Data. No data submitted.

Exposure. Dermal and inhalation, a total of 10 workers, up to 1 hr/da, up 5 da/yr.

Environmental Release/Disposal. No release.

TME 83-32

Manufacturer. Confidential.

Chemical. (G) Ployester polyurethane.

Use/Production. (G) Open use. Prod. range: 11,200 (max) kg/yr.

Toxicity Data. No data submitted.

Exposure. Manufacture: a total of 27 workers, up to 6 hrs/da, up 6 da/yr; processing: dermal and ocular, a total of 15 workers, up to 6 hrs/da, up to 6 da/yr; Use: dermal and ocular, 6 workers 8 hrs/da, 45 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 10-100 to land. Disposal by incineration and landfill.

TME 83-33

Manufacturer. Confidential.

Chemical. (G) Disubstituted heteromonocycle.

Use/Production. (G) Open use. Prod. range: 4,480 (max) kg/yr.

Toxicity Data. No data submitted.

Exposure. Manufacture: a total of 27 workers, up to 6 hrs/da, up 6 da/yr; processing: dermal and ocular, 48 workers, up to 6 hrs/da, up to 6 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 10-100 to land. Disposal by incineration.

Dated: March 18, 1983

Linda A. Travers,

Acting Director, Management Support Division

[FR Doc. 83-7823 Filed 3-24-83; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-51459; TSH-FRL 2330-3]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the Federal Register of May 15, 1979 (44 FR 23558) and November 7, 1980 (45 FR 74378). This notice announces receipt of twenty PMNs and provides a summary of each.

DATES: Close of Review Period:

PMN 83-550, 83-551 and 83-552: June 8, 1983.
PMN 83-553, 83-554 and 83-555: June 11, 1983.
PMN 83-556, 83-557, 83-558, 83-559, 83-560, 83-561, 83-562, 83-563 and 83-564: June 12, 1983.
PMN 83-565: June 13, 1983.
PMN 83-566, 83-567, 83-568 and 83-569: June 14, 1983.

Written comments by:

PMN 83-550, 83-551, and 83-552: May 9, 1983.
PMN 83-553, 83-554 and 83-555: May 12, 1983.
PMN 83-556, 83-557, 83-558, 83-559, 83-560, 83-561, 83-562, 83-563 and 83-564: May 13, 1983.
PMN 83-565: May 14, 1983.
PMN 83-566, 83-567, 83-568 and 83-569: May 15, 1983.

ADDRESS: Written comments, identified by the document control number "(OPTS-51459)" and the specific PMN number should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm E-409, 401 M St., SW., Washington, DC 20460, (202-382-3532).

FOR FURTHER INFORMATION CONTACT: Theodore Jones, Acting Chief, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm E-216, 401 M St., SW., Washington, DC 20460, (202-382-3729).

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete non-confidential document is available in the Public Reading Room E-107.

PMN 83-550

Manufacturer. Confidential.

Chemical. (G) Polymer of formaldelhyde and substituted phenols.

Use/Production. Confidential. Prod. range: Confidential.

Toxicity Data. No data submitted.

Exposure. Confidential.

Environmental Release/Disposal. Confidential.

PMN 83-551

Manufacturer. Confidential.

Chemical. (G) Modified polymer of formaldehyde and substituted phenols.

Use/Production. Confidential. Prod. range: Confidential.

Toxicity Data. No data submitted.

Exposure. Confidential.

Environmental Release/Disposal. Confidential.

PMN 83-552

Manufacturer. Monsanto Company.

Chemical. (G) Phenol formaldehyde butanol resin.

Use/Production. (S) Crosslinking agent for industrial epoxy and polyacetal coating systems. Prod. range: Confidential.

Toxicity Data. Acute oral: >5.010 mg/kg; Acute dermal: >5.010 mg/kg; irritation: Skin—Non-irritant, Eye—Moderate.

Exposure. Manufacture: dermal, inhalation and ingestion, a total of 6, workers accidental.

Environmental Release/Disposal. Released to air and land. Disposal by approved hazardous waste facility.

PMN 83-553

Importer. Ilford, Incorporated.

Chemical. (S) Ethanesulfonic acid, 2-bis (2-cyanoethyl) phosphino]—potassium salt.

Use/Import. (S) Catalyst in photographic processing solution. Import range: 1,800–2,600 kg/yr.

Toxicity Data. Acute oral: 8,340 mg/kg; Irritation: Skin—Marked, Eye—Minimal; EC_{50}, 24 hr (Daphnia magna): 413.7 mg/L; Biodegradation: Not readily biodegradable; Salmonella and Eschericha/Liver Microsome Test: Negative; LC_{50} (Zebra fish) 96 hr: >1,000 mg/L.

Exposure. Manufacture: a total of 5–7 workers, up to 300 manhours/yr.

Environmental Release/Disposal. Disposal by public and private sanitary waste water treatment facilities.

PMN 83-554

Manufacturer. Confidential.

Chemical. (G) 1,3-benzenedicarboxylic acid, 5-substituted, polymer with 1,2-ethanediol and oxo-heteropolycycle.

Use/Production. (G) Industrial resin. Prod. range: Confidential.

Toxicity Data. Acute oral: >5.000 mg/kg; Irritation: Skin—Slight, Eye—Minimal; Ames Test: Negative.

Exposure. Manufacture, processing and use: dermal and inhalation, a total of 10 workers, in 8 hr/shifts, 20 times/yr.

Environmental Release/Disposal. No release. Disposal by incineration.

PMN 83-555

Manufacturer. Confidential.

Chemical. (G) 1,3-benzenedicarboxylic acid, 5-substituted, polymer with 1,2-ethanediol and oxo-heteropolycycle.

Use/Production. (G) Industrial resin. Prod. range: Confidential.

Toxicity Data. Acute oral: >5.000 mg/kg; Irritation: Skin—Non-irritant, Eye—Minimal; Ames Test: Positive.

Exposure. Manufacture, processing and use: dermal and inhalation, a total of 6 workers, in 8 hr/shifts, 20 times/yr.

Environmental Release/Disposal. No release. Disposal by incineration, landfill and publicly owned waste treatment facility.

PMN 83-556

Manufacturer. Confidenial.

Chemical. (G) Polyester polyurethane.

Use/Production. (G) Open use. Prod. range: 1,000–200,000 kg/yr.

Toxicity Data. No data submitted.

Exposure. Manufacture, processing and use: dermal and ocular, a total of 102 workers, up to 8 hrs/da, up 240 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 10–1,000 kg/yr to land. Disposal by incineration and approved landfill.

PMN 83-557

Manufacturer. Confidential.

Chemical. (G) Disubstituted heteromonocycle.

Use/Production. (G) Open use. Prod. range: 400–90,000 kg/yr.

Toxicity Data. No data submitted.

Exposure. Manufacture and processing: dermal and ocular, a total of 156 workers, up to 6 hrs/da, up 18 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 10–1,000 kg/yr to land. Disposal by incineration, approved landfill or sold as fuel.

PMN 83-558

Manufacturer. Confidential.

Chemical. (G) Modified epoxy resin.

Use/Production. (G) Open use. Prod. range: 40–9,000 kg/yr.

Toxicity Data. No data submitted.

Exposure. Manufacture, processing and use: dermal and ocular, a total of 54 workers, up to 6 hrs/da, up 250 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 10–100 kg/yr to land. Disposal by incineration.

PMN 83-559

Manufacturer. Celanese Corporation.

Chemical. (G) Organo phosphate.

Use/Production. (G) Open use. Prod. range: 1,000–10,000 kg/yr.

Toxicity Data. No data on the PMN substance submitted.

Exposure. Manufacture and processing: dermal, a total of 12 workers, up to 8 hrs/da, up 240 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air, water and land. Disposal by incineration, landfill and recycling.

PMN 83-560

Manufacturer. Celanese Corporation.

Chemical. (G) Organo phosphate polymer.

Use/Production. (G) Open use. Prod. range: 1,000–10,000 kg/yr.

Toxicity Data. No data on the PMN substance submitted.

Exposure. Manufacture: dermal, a total of 12 workers, up to 8 hrs/da, up 240 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air, water and land. Disposal by incineration, landfill and recycling.

PMN 83-561

Manufacturer. E. I. du Pont de Nemours & Co., Inc.

Chemical. (G) Acrylic alkyd polymer.

Use/Production. Confidential. Prod. range: Confidential.

Toxicity Data. No data submitted.

Exposure. Manufacture: dermal, 2 persons/shift, 8 hrs/shift, 3 shifts/da, 1.4 da/yr.

Environmental Release/Disposal. Disposal by incineration.

PMN 83-562

Manufacturer. E. I. du Pont de Nemours & Co., Inc.

Chemical. (G) Acrylic alkyd polymer.

Use/Production. Confidential. Prod. range: Confidential.

Toxicity Data. No data submitted.

Exposure. Manufacture: dermal, 2 persons/shift, 8 hrs/shift, 3 shifts/da, 2.5 da/yr.

Environmental Release/Disposal. Disposal by incineration.

PMN 83-563

Importer. Confidential.

Chemical. (G) Substituted indolium, salt.

Use/Production. (S) Colorant for textiles and papers. Import range: Confidential.

Toxicity Data. No data submitted.

Exposure. Use: Negligible.

Environmental Release/Disposal. No release.

PMN 83-564

Manufacturer. Confidential.

Chemical. (G) Dialkyl cycloaliphatic diester.

Use/Production. (G) Chemical intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral: > 3,000 mg/kg; Acute dermal: > 1,000 mg/kg; Irritation: Skin—Slight, Eye—Slight; Skin sensitization: Low potential.

Exposure. Manufacture: dermal and inhalation, a total of 32 workers, up to 3 hrs/da, up 50 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air and water. Disposal by biological treatment system and incineration.

PMN 83-565

Manufacturer. Confidential.

Chemical. (G) Sodium salt of a polymer of acrylic acid, acrylamide, and substituted acrylamide.

Use/Production. (S) Industrial flocculent in waste treatment and processing mineral streams. Prod. range: Confidential.

Toxicity Data. No data submitted.

Exposure. Manufacture and use: dermal, less than 5 workers, up to 24 hrs/da, up 365 da/yr.

Environmental Release/Disposal. 10–100 kg/yr released to water with more than 10,000 kg/yr to land.

PMN 83-566

Manufacturer. E. I. du Pont de Nemours & Co., Inc.

Chemical. (G) Substituted chlorobenzene.

Use/Production. (G) Captive intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral: 2,250 mg/kg; Irritation: Skin—Moderate, Eye—Non-irritant; Ames Test: Non-mutagenic; Skin sensitization: Non-sensitizer.

Exposure. Manufacture: minimal.

Environmental Release/Disposal. No release.

PMN 83-567

Manufacturer. Confidential.

Chemical. (G) Modified acrylic copolymer.

Use/Production. Confidential. Prod. range: Confidential.

Toxicity Data. No data submitted.

Exposure. Confidential.

Environmental Release/Disposal. Confidential.

PMN 83-568

Manufacturer. Confidential.

Chemical. (G) Substituted styrene.

Use/Production. (S) Chemical intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral: > 2 g/kg; Irritation: Skin—Moderate, Eye—Very slight.

Exposure. Manufacture: dermal and inhalation, a total of 16 workers.

Environmental Release/Disposal. No release. Disposal by incineration.

PMN 83-569

Manufacturer. Confidential.

Chemical. (G) Phenyl substituted butane.

Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral: 5 g/kg; Irritation: Skin—Moderate, Eye—Slight.

Exposure. Manufacture: dermal, a total of 16 workers.

Environmental Release/Disposal. No release. Disposal by incineration.

Dated: March 18, 1983.

Linda A. Travers,

Acting Director, Management Support Division.

[FR Doc. 83-7622 Filed 3-24-83; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL MARITIME COMMISSION

[Docket No. 83-17]

Rates Applicable to Ocean Shipments Via OOCL-Seapac Service; Filing of Petition for Declaratory Order

Notice is given that a petition for declaratory order has been filed by the Pacific Westbound Conference and OOCL-Seapac Service to allow OOCL-Seapac to act without peril upon its view that certain rate increases ought not to be paid by offerted shippers. The circumstance giving rise to the petition was the cancellation of certain per-containers rates which led to rate increases being inadvertently implemented on less than statutory notice.

Interested persons may inspect and obtain a copy of the petition at the Washington Office of the Federal Maritime Commission, 1100 L St., N.W., Room 11101. Participation in this proceeding by persons not named in the petition will be permitted only upon grant of intervention pursuant to Rule 72 of the Commission's Rules of Practice and Procedure (46 CFR 502.72).

Petitions to intervene shall be accompanied by intervenor's complete reply in the matter. Such petitions and any replies to the petition for declaratory order shall be filed with the Secretary on or before April 21, 1983. An original and fifteen copies shall be submitted and a copy served on all parties. Replies shall contain the complete factual and legal presentation of the replying party as to the desired resolution of the petition for declaratory order.

Francis C. Hurney,

Secretary.

[FR Doc. 83-7764 Filed 3-24-83; 8:45 am]

BILLING CODE 6730-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770–776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meeting is announced:

Fertility and Maternal Health Drugs Advisory Committee, FDA, and the Center for Population Research, NICHD/NIH—Workshop on the Animal Testing Requirements for Evaluating the Long-Term Safety of Steroid Contraceptives

Date, time, and place. April 27 and 28, 9 a.m.; April 29, 7:30 a.m., Conference Rm. 10, 6th Floor, Bldg. 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. Open public hearing, April 27 and 28, 9 a.m. to 5 p.m.; closed committee deliberations, April 29, 7:30 a.m. to 9:30 a.m.; open public hearing, April 29, 10 a.m. to 5 p.m.; A. T. Gregoire, National Center for Drugs and Biologics (HFN-130), 5600 Fishers Lane, Rockville, MD 20857, 301–443–1869; Richard Blye, Center for Population Research, 7010 Woodmont Ave., Bethesda, MD 20205, 301–496–1661.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drug products for use in obstetrics, gynecology, and contraception.

Agenda—open public hearing. Any interested person may present data, information, or views, orally or in writing, on issues pending before the committee.

The committee in conjunction with the Center for Population Research (NICHD/NIH) and with the cooperation of the World Health Organization, the Population Council,

socma

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, INC.
1612 K STREET, N.W., SUITE 306, WASHINGTON, DC 20006 • (202) 659-0060

TESTIMONY OF MICHAEL J. SCOTT

GENERAL COUNSEL OF MOONEY CHEMICALS, INC.

and

CHAIRMAN, TOXIC SUBSTANCES COMMITTEE, SOCMA

Before the

SENATE COMMITTEE ON ENVIRONMENT & PUBLIC WORKS

SUBCOMMITTEE ON TOXIC SUBSTANCES

AND ENVIRONMENTAL OVERSIGHT

July 28, 1983

NEW YORK OFFICE: 1075 CENTRAL PARK AVENUE, SCARSDALE, NY 10583 (914) 725-1492

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SMALL BUSINESS DEFINITION UNDER SECTION 8(a) RULES.......... APPENDIX B

Mr. Chairman, and distinguished members of ths Subcommittee, I am Michael J. Scott, General Counsel of Mooney Chemicals, Inc. I appear today on behalf of Mooney Chemicals which is a small manufacturer of specialty chemicals based in Cleveland, Ohio. I also appear on behalf of the Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA) whose Toxic Substances Committee I chair. I want to thank the Subcommittee for this opportunity to present the views of Mooney Chemicals and SOCMA on the implementation of the Toxic Substances Control Act (TSCA).

SOCMA is a non-profit trade association representing over 100 organic chemical companies, the majority of which are small companies with annual organic chemical sales under $30,000,000. The members of SOCMA produce more than 5,000 distinct synthetic organic products which are primarily intermediates and finished chemicals for industrial use. A list of the member companies is attached as Appendix A.

Small chemical manufacturers have had a number of concerns about the administration and implementation of TSCA. Among those concerns, we believe EPA needs to examine the cumulative effects of the entire TSCA program on small business and to establish an integrated small business policy to reduce unnecessary burdens. We also believe that the final premanufacture notification (PMN) rule which EPA has recently issued is unduly burdensome in certain respects and should be revised to avoid unnecessarily impeding innovation by small business. We further think that there is room for improvement in EPA's procedures for handling confidential business information submitted under TSCA.

While EPA needs to act on these concerns, my testimony today will focus on four specific points that are of paramount importance to small chemical companies. These are:

(1) the high cost of compliance with PMN requirements by small chemical companies inhibits innovation by such companies;

(2) a PMN exemption for low volume chemicals and site-limited intermediates is needed to help reduce the burden of PMN requirements on small company innovation;

(3) a consistent definition of small business in TSCA rules is needed to lessen reporting and recordkeeping burdens on small companies; and

(4) the PMN review and follow-up mechanisms provided under TSCA are adequate to prevent unreasonable risks so that the statutory PMN information requirements do not need to be changed.

We believe that the measures recommended by SOCMA to mitigate the adverse impact of TSCA on small business would not result in any unreasonable risks developing.

I. THE COST OF COMPLIANCE WITH PMN REQUIREMENTS BY SMALL BUSINESS

One of the basic issues in the operation of the PMN program is whether and to what extent PMN requirements have had an impact on the rate of innovation by small chemical companies. This section of the testimony describes how small firms develop and market their products. It examines the existing studies that show the significant adverse impact of TSCA and, in particular, the PMN program on small companies. It also summarizes SOCMA's views on the differential impact of PMN requirements on small business in contrast to large businesses. The later sections of this testimony show how these adverse economic effects on small firms can be mitigated without engendering unreasonable risk.

Development of Products by Small Chemical Manufacturers

The typical small chemical company is a manufacturer of specialty products that are utilized for a particular application in contrast to the manufacturer of bulk commodity chemicals from primary raw materials. The specialty manufacturer is an important part of both the domestic and international chemical industry. Briefly stated, its role is to produce a large number of low-volume chemicals for a limited number of industrial users. Its customers are generally limited to a relatively small number of technically competent firms.

Between 90 - 95% of the number of chemical companies in the U.S. are small in that they have less than $30 million in sales. This segment of the industry includes over 10,000 firms. However, looking at the industry as a whole, small business accounts for only 10 - 15% of the employment and about 10% of the sales of chemical manufacturers.

In profile, small chemical companies are:

- Innovative -- measured by innovations per employee, small companies are more innovative than large companies.
- Entrepreneurial -- operated by people who believe they can make a better product, and who are familiar with the properties of their chemicals.
- Producers of a Limited Product Line of Specialty Chemicals in a Narrow Spectrum of Chemistry - often it is the sole producer of many of its products.
- Oriented to Serve a Limited Segment of the Industry and Limited Number of Customers in a Market Niche
- Management Time is Fully Utilized -- each professional wears many hats.
- Lacking in Economics of Scale for Purchasing, Manufacturing and Selling
- Willing and Able to Venture Where Large Companies Cannot Go Economically -- small volume, custom manufacturer.

The type of innovation conducted by the small chemical manufacturer most typically involves a slight change in an existing substance for use by an individual customer in small volumes. Studies conducted by EPA of PMN's submitted by firms with less than $100 million in sales (the smallest sales category examined) indicate that 62% of small business PMN's are for production volumes of less than 10,000 kilograms per year. 31% of small business PMN's are for chemicals with production volumes of less than 1,000 kilograms per year.1/ As detailed

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1/ EPA's Office of Pesticides and Toxic Substances, "Economic Impact Analysis of TSCA Section 5(h)(4) Exemptions: Low-Volume Chemicals" 13 (Apr. 1982).

below, these chemicals often generate low revenues which cannot profitably cover high PMN costs.

Studies of Small Business Innovation and TSCA

SOCMA has long contended that small companies are very innovative and that TSCA is having a serious adverse impact on innovation. SOCMA's belief that small companies are generally innovative has recently been documented in several studies. In a report prepared for the Office of Advocacy of the Small Business Administration (SBA), Gellman Research Associates, a firm well known for its research on innovation, examined 635 innovations in a wide number of industries, including the chemical industry. The report found that:

1. Small firms produce 2.5 times as many innovations as large firms, relative to the number of people employed.
2. Small firms require less time to take an innovation from performance specification to market introduction.2/

Significantly, a recent study by Edward Heiden and Alan Pittaway of the Regulatory Research Service found that small chemical specialties companies (under $100 million in annual sales) introduced many more new chemicals than larger companies in the years prior to the effective date of PMN

2/ SBA's Office of Advocacy, The Relationship Between Industrial Concentration, Firm Size and Technological Innovation 5 (May 1980) (Prepared by Gellman Research Associates).

requirements.[3/] Thus, these studies establish the nexus between small chemical companies and innovation.

Recent studies also document that the PMN program has caused a reduction in innovation by small firms. The Heiden-Pittaway study found that TSCA has reduced the number of new substances introduced by certain small chemical companies by 26 percent.[4/] This reduction occurred largely because small companies typically produce low volume chemicals which have lower profit potential.[5/] ICF, in its 1983 regulatory impact analysis of the PMN rule, documented the low number of PMN's submitted by small companies since Section 5 became effective. It found that firms with annual sales of less than $30 million submitted only 6.7% of all PMN's and firms with annual sales of less than $100 million submitted only 13.6% of all PMN's.[6/]

Where small companies intend to produce higher volume chemicals (e.g. 100,000 Kg), ICF found that these companies would not be significantly affected by PMN costs in a "best case" analysis.[7/] However, as ICF notes, "because this analysis

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[3/] Impact of the Toxic Substances Control Act on Innovation in the Chemical Specialties Manufacturing Industry II-6, II-8 (Dec. 1981) (Prepared for Chemcial Specialties Manufacturers Association).

[4/] Id. at 1-2.

[5/] See id. at IV-11.

[6/] ICF, Inc., "Regulatory Impact Analysis for New Chemical Reporting Alternatives Under Section 5 of TSCA" 156 (May 1983) (hereinafter "ICF").

[7/] See id. at 154-55.

is based on chemicals which, by definition, were those submitted by small firms which could absorb the costs and remain profitable, the cost estimates would be biased downward."[8/] As a result, the adverse effects estimated by ICF in the best case could be understated. In its "worst case" analysis, ICF found that PMN costs would have a significant adverse impact on small business.[9/]

A simple example illustrates why PMN requirements so greatly influence small business innovation, and thus why the number of PMN's submitted by small business has been so low. Taking the highest price for chemicals considered in the ICF regulatory impact analysis of the PMN rule -- a price of $2.00/kg -- a substance produced in a quantity of 1,000 kg would result in $2,000 gross revenues. ICF conservatively estimates that the final PMN rule will cost between $5,400 and $12,700 to complete,[10/] or from two to six times the expected gross revenue at the hypothesized price. In essence, the costs of submitting a PMN are very high in relation to the expected revenues of a low-volume chemical in the initial stages of commercialization.

[8/] *Id.* at 163.

[9/] *Id.* at 155.

[10/] *Id.* at 154. This $2.00/kg figure may be compared with the 1980 average sales price of organic chemicals, which was $.95/kg. International Trade Commission, *Synthetic Organic Chemicals* 4 (1980).

This example illustrates that the regulatory costs associated with PMN requirements are significant in relation to the gross revenue (not to mention net revenues after other costs of business) generated from low-volume chemicals, the market niche in which small companies typically operate. Clearly, only very highly priced low-volume chemicals can support these regulatory costs. Thus, the weight of the evidence indicates a significant adverse impact on small business innovation from PMN requirements.

Differential Impacts on Small Business

The impact of the PMN program described above weighs most heavily on small businesses in comparison to large firms. In other words, the costs of PMN requirements to small firms are larger per dollar of sales than for large firms. As an economic analysis conducted for EPA states:

> Small firms would be expected to sustain the greatest relative impact from PMN costs due to their more limited resources and less legal/regulatory expertise compared to large firms.[11]

Similarly, the Heiden-Pittaway study also reported a disproportionate impact on small companies. It found:

> the impact of PMN costs falls almost entirely, and heavily on smaller firms, mostly producing ingredients in smaller sale size classes, with lower minimum target profit levels per innovation. Even though filing

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11/ Economic Analysis of TSCA Section 5(h)(4) Exemptions, 27.

> costs are assumed to be up to 37 percent lower for small firms (i.e., those below $100 million in overall sales), these smaller firms would on the average have an almost fifty times greater probability of rejecting an innovation for PMN cost reasons than would firms in larger overall size classes (above $200 million) (emphasis added).[12]

As illustrated by the example used previously, the adverse PMN impact on small companies primarily results from the low volume, low revenue chemicals they typically manufacture. The ICF regulatory impact analysis explains this impact:

> the major effect of the rule is selective; some of the small volume, lower value chemicals probably can not absorb even the relatively low reporting burden represented by the most recent EPA proposals. (Exemptions should significantly reduce this burden).[13] (Emphasis added)

Not only is the compliance cost burden disproportionate for small businesses, but so too is the financial risk of the investment in innovation higher for small firms. In short, more is at stake for small businesses.

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[12] Impact of the Toxic Substances Control Act on Innovation in the Chemical Specialties Manufacturing Industry IV-11 (Dec. 1981) (Prepared for Chemical Specialties Manufacturers Association).

[13] ICF at 132.

II. THE NEED FOR PMN EXEMPTIONS

In view of the effect of TSCA on innovation by small firms, it is essential that EPA promptly issue a final PMN rule under Section 5(h)(4) of TSCA. EPA's issuance of a PMN exemption rule for certain chemicals which do not pose an unreasonable risk would greatly minimize the adverse impact of PMN requirements. We believe that such a rule would be completely consistent with the objectives of the Act.

As the House Committee on Energy and Commerce noted two years ago, EPA's promulgation of Section 5(h)(4) exemptions for certain chemical groups is "important from the standpoint of both agency resources and manufacturers cost." H.R. Rep. No. 97-86 at 7 (May 19, 1981). The report concluded: "The Committee finds that the Agency could allay many of the concerns regarding the purported adverse effects of Section 5 by expeditiously developing a series of exemptions under Section 5(h)(4)." Id. at 8.

The Proposed Exemption Rule

EPA issued, last August, a proposed PMN exemption for certain low volume chemicals and site-limited intermediates if a qualified expert determined that the new chemical does not present a carcinogenic or teratogenic risk and, under its conditions of production and use, does not present other significant health or environmental risks. The proposal also provides a very low volume tier which would exempt chemicals under 1,000 kg per year if the company could certify, after its own review, that the chemical would not present significant health or environmental risks under its conditions of production and use. In all cases, a manufacturer seeking a PMN exemption would have to submit a notice of such exemption to EPA at least 14 days prior to manufacture of the new chemical. The Agency then must conduct its own review. If at some later time, a manufacturer wanted to exceed the 10,000 kg per year limit of the low volume PMN exemption or use a site-limited intermediate in a non-exempt manner, a full blown PMN submission would be required before doing so.

Effect of the Proposed Exemption on Small Business

This much needed PMN exemption would significantly reduce the cost of PMN requirements for many new chemicals and would allow small companies to respond to immediate customer needs without a 90 day PMN delay. Where a chemical has completed a period of commercial production under the exemption conditions which ensure no unreasonable risk, the manufacturer would have a better understanding prior to filing a PMN of the commercial application and the exposure potential which may exist. The Agency would thus receive more complete data in PMNs for such substances than it is possible to provide today because of the statutory requirement that a PMN be submitted before manufacture commences. This approximates the "pay as you go" approach that SOCMA has urged EPA to adopt in its PMN program.

No Unreasonable Risk Would Result from Promulgation of an Exemption

At the same time, SOCMA firmly believes that the contemplated PMN exemption would provide more than adequate protection against chemicals which may present an unreasonable risk to health and environment. Because of the low volume nature of an eligible chemical and the site-limited nature of an eligible intermediate, virtually all exempted chemicals would not present significant exposure to health or the environment. Furthermore, the automatic exclusion for carcinogenic or teratogenic effects, the qualified expert review, and the 14 day review by EPA would ensure that chemicals which may raise health and environmental issues are identified and excluded. Thus, adequate safeguards are provided to ensure that both exposure and toxicity aspects of the new chemical are adequately evaluated.

In addition, SOCMA strongly supports the abbreviated PMN exemption process in the proposal for very low volume chemicals produced in quantities of 1,000 kg per year or less. For a PMN exemption to be beneficial to small companies, the cost and complexity of qualifying for it must be kept to a minimum. Dr. J. Clarence Davies, representing the Conservation

Foundation, described the soundness of a 1,000 kg PMN exemption before a hearing of this subcommittee last year:

> We do agree in principle with the notion that you can exempt some categories of chemicals and not worry too much about incurring unreasonable risk. We believe that to exempt chemicals manufactured in quantities of less than 1,000 kilograms per year, is probably sound policy.[14]

Dr. Davies also stated that: "The impact on small business is an important part of the exemption policy and that is one of the reasons the 1,000 kilgram exemption makes sense."[15]

Often small companies make very low volume chemicals for sophisticated industrial customers which generate only $1,000-$5,000 in annual revenues. By allowing a company to rely on an in-house staff review to certify that the PMN exemption requirements for very low volume chemicals are satisfied, this PMN exemption tier would eliminate any need there may be for small companies to hire expensive toxicologists or other professional consultants to conduct the qualified expert review required for the other proposed exemption certification. This review would be based on their intimate knowledge of the low exposure conditions involved and their familiarity with the narrow range of chemicals from which the very low volume chemical typically emanates. The low exposure characteristics of these chemicals typically would minimize any risks associated with them. In addition, EPA would then have a 14 day review period to ensure that the new chemicals meets the PMN exemption terms.

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[14] Hearings on the Implementation of the Toxic Substances Control Act Before the Subcommittee on Toxic Substances and Environmental Oversight of the Senate Committee on the Environment and Public Works, (97th Cong. 2nd Sess. 17 (1982)).

[15] Id. at 28.

Overall, this very low volume tier would provide significant relief for small chemical companies while ensuring that the health and environmental attributes of the new chemical have been adequately reviewed.

III. THE NEED FOR A CONSISTENT DEFINITION OF SMALL BUSINESS

In the past, one of SOCMA's major concerns with EPA's implementation of TSCA has been the narrow, rule by rule manner in which the Agency has defined small business for purposes of the small business exemption from routine reporting and recordkeeping requirements under Section 8(a).16/ EPA's ad hoc approach, which has included a small business definition as low as $500,000 in annual sales, has created much uncertainty about whether a company is considered small for a particular rule and has required companies to check each individual rule. Moreover, the rule by rule approach has ignored the significant

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16/ Appendix B sets out the various definitions that EPA has used.

cumulative impact that reporting rules can have on small companies. Filling out complex government forms is a time consuming and difficult task for small companies which lack the administrative personnel to take care of such matters. For these reasons, the House Committee report for the 1980 TSCA reauthorization bill directed the Agency "to pursue promulgation of [a small business definition] with all necessary speed." H.R. Rep. No. 96-968 at 6-7. This small business definition has not yet been promulgated.

The Proposed Definition

Last June, EPA issued a proposed definition of small manufacturers for use in most Section 8(a) reporting and recordkeeping rules. SOCMA believes that this proposal represents an important step to simplify the burden of complying with Section 8(a) rules. We also believe that the small business definition should be used to provide exemptions or other appropriate relief for small business from other TSCA reporting and recordkeeping rules. The use of such exemptions should be an integral part of EPA's overall policy of minimizing the impact of TSCA requirements on small companies, as required by the Regulatory Flexibility Act.

Under EPA's proposed small business definition, Section 8(a) rules would not apply to (1) manufacturers having less than $30 million in annual sales of a chemical subject to the rule, provided they produce annually less than 100,000 pounds of the chemical at any one site, and (2) a l manufacturers having less than $3 million in annual sales, regardless of production volume. We believe that the sales levels in this proposal need to be revised upward somewhat to account for inflation and that the final small business rule should provide for an automatic annual adjustment of these levels to account for inflation.[17]

No Unreasonable Risk Would Result from Promulgation of the Recommended Definition

Issuance of a small business definition along the lines of SOCMA's recommendations would not result in significant information losses. For example, EPA has determined that using exemption levels of $40 million and 100,000 pounds would result in no reports being filed for only about 10 percent of the chemicals analyzed and would exempt only about 8.5 percent of the total number of plant sites.[18] Yet, based on ICF's analysis of small business definitions, the use of such exemption parameters would reduce the cost to small companies of complying with section 8(a) rules by about 60 percent.[19]

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[17] SOCMA has proposed that $40 million in annual sales revenue and 100,000 pounds of annual production at one site be used in the first exemption tier and $6.5 million in annual sales be used in the second tier.

[18] *See* 47 *Fed. Reg.* 27205, 27210-11 (June 23, 1983). Significantly, the use of a $40 million exemption level instead of EPA's proposed $30 million level increases the percentage of no report chemicals by only .5 percent and increases the percentage of exempt plant sites by only .2 percent. *Id.* Similarly, the use of a $6.5 million exemption level instead of EPA's proposed $3 million level would increase the percentage of zero-report chemicals by only .5 percent. *See* ICF, Inc. "Analysis of TSCA Section 8(a) Small Manufacturers Exemption" Exhibit 4-25 (1982).

Moreover, section 8(a) allows EPA to require reports and recordkeeping by small companies for chemicals subject to a section 5(e) insufficient information order, a section 4 test rule, control actions under sections 5, 6, or 7, a lawsuit under sections 5 or 7, and chemicals on the section 5(b)(4) risk list. Thus, the Agency has ample authority to collect information from small companies on certain chemicals which involve unreasonable risks.

SOCMA believes that the Agency should move immediately to finalize the proposed rule, with the changes recommended by SOCMA. This definition should be used for all section 8(a) rules, except in the circumstances specified in the statute. We ask the Committee to encourage EPA to issue this needed rule.

IV. ADEQUACY OF PMN REQUIREMENTS

The question has arisen whether the PMN data requirements are sufficient to allow EPA to perform an adequate health and environmental evaluation of a new chemical. Two recent studies--one by OTA and another by ICF--have evaluated the PMN information submitted on new chemicals. As explained below, meaningful conclusions about the adequacy of PMN data cannot be drawn from the OTA study because of the methodology used. In contrast, the ICF study, using a more appropriate methodology, indicates that information required by the final PMN form is sufficient to identify risks about which the Agency is concerned. In those cases where inadequate PMN information is submitted, section 5(e) provides EPA with ample authority, which it uses, to require additional information to adequately evaluate the risks of a new chemical. Thus, we believe that the present PMN review and follow-up mechanisms under TSCA are sufficient to prevent unreasonable risks. At the same time, it is sufficiently flexible to allow PMN submissions to be tailored to the specific hazard and exposure characteristics of the new chemical.

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[19] The ICF analysis estimates that if $50 million and 100,000 pounds are used as exemption levels, the total costs to manufacturers with annual sales under $50 million for complying with section 8(a) rules would be reduced by 64 percent. "Analysis of TSCA Section 8(a) Small Manufacturers Exemption" 5-11 (1982).

The OTA Report

The OTA study identified 45 items for which data might be submitted on PMN's.[20/] The presence or absence of each of the 45 items was recorded and the frequency of submission of the items for all PMN's and some subsets was computed.

[20/] OTA, "The Information Content of Premanufacture Notices: Background Paper" (1983).

OTA concluded that over 90% of PMN's contained the required information about the identity of the chemical, its expected production volume, its likely uses, the number of workers who might be exposed, and methods for disposal. 86% reported all TSCA-specified information except for byproduct data, which was contained in 67% of PMN's.

OTA looked at physical-chemical and toxicity information reported on some subgroups of PMN's and found more frequent reporting on PMN's that describe substances that are more likely to be hazardous.

However, the OTA report notes that:

> These generally positive observations must be tempered by the fact that about half of PMN's reported no toxicity information. Furthermore, only 17% of PMN's have any test information about the likelihood of the substance's causing cancer, birth defects or mutations--three biological effects that were singled out for special concern in TSCA.[21/]

Despite that fact, OTA finds that "more PMN information is being submitted about worrisome groups of chemicals" than about groups for which there is less concern.[22/] The report states:

> . . . There is, as shown in this paper, a tendency for information to be submitted for substances likely to be more hazardous or to result in more widespread exposures. For instance, toxicity data are submitted more frequently on PMN's that describe

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[21/] *Id*. at 6.

[22/] *Id*.

> nonpolymers, which as a group are more likely to be more hazardous, than on PMN's that describe polymers; more data are submitted on PMN's that observations are consistent with the idea that companies develop and report appropriate data to EPA.[23]

However, drawing definitive conclusions from the OTA study about the overall adequacy of PMN data is impossible because of the methodology chosen to conduct the study. The methodology used was simply to determine the quantity of certain kinds of PMN information submitted and then to compare such information quantity for new chemicals in different categories (*e.g.*, polymers v. non-polymers, high volume v. low volume, consumer use v. industrial use). *Yet, simply counting PMN data points for chemicals in different categories is an inappropriate method for determining the sufficiency of PMN data unless the crucial role of risk assessment is properly included to determine both the hazard and exposure characteristics of a chemical.*

The data relevant for reviewing the likely risks of one kind of chemical are not necessarily relevant to the potential risks posed by another kind of chemical. Thus, the absence of data in one instance may prevent an adequate evaluation of a new chemical's risks, but not be relevant to the evaluation of another new chemical. The failure of the OTA study to consider such hazard and exposure differences among new chemicals is an inherent flaw in that study.

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[23] *Id.*

OTA addresses this criticism by suggesting the type of study needed:

> Answering those questions would require an examination of EPA's decisionmaking process about at least some PMN's on a case-by-case basis. That study would be different from the one reported here, and would involve a process similar, in some regards, to that used by EPA to review PMN's. A group of scientists would review the data on the PMN's, supplement that information with other information available from the scientific literature and experts, decide if EPA's decision was appropriate, and ask whether additional information on the PMN might have made a difference in the decision.[24/]

On a small scale, ICF performed a type of analysis in its regulatory impact analysis of Section 5 requirements which was similar to what OTA envisioned. Although ICF's method and conclusions are not indicative of the entire PMN program, they form an interesting case study comparison to the OTA report.

The ICF Study

ICF, in its regulatory impact analysis of Section 5 rules, studied the health implications of regulatory actions resulting from alternative PMN reporting forms.[25/] A careful

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[24/] *Id.* at 6.

[25/] ICF, Inc., "Regulatory Impact Analysis for New Chemical Reporting Alternatives Under Section 5 of TSCA" 164-195 (May, 1983).

review was carried out by a senior EPA scientist with substantial experience in the PMN review process; reviews were conducted for 14 of the 64 PMN's for which the Agency informally or formally had expressed concerns about possible risks. The objective was to determine the potential for different regulatory outcomes that would result from the use of alternative PMN forms. Thus, the ICF analysis examines the heart of the issue, *i.e.*, whether the regulatory outcome changes as a result of different PMN information being submitted.

ICF concludes that the design of the current EPA form under the final rule would result in a prevention of the risks posed by the suspect chemicals examined in the study; that is, a correct decision would be made as a result of the use of the final PMN form. The ICF study points to the crucial role of EPA staff in reviewing PMN's and the staff's ability to obtain needed information where it is lacking.

While the study does not represent a general analysis of the PMN program, it does provide insights into the deficiencies of the OTA study. The central issue is whether a different regulatory outcome would result if additional or less information were submitted with a PMN. The ICF study reflects the conclusion that the level of information required on the final form together with the expertise of EPA is sufficient to detect potential unreasonable risks. While SOCMA believes that certain aspects of the PMN rule and form should be clarified or changed, such actions would not influence the analysis of regulatory outcomes reviewed above.

Significantly, ICF also comments on the overall effectiveness of the PMN program.

> It is difficult to predict how hazardous the newly-introduced chemicals would have been over the period covered by this analysis in the absence of the PMN program, but we suspect that the deterrent effect of the program in preventing the introduction of such substances into commerce has been great. It is highly probable that the existence of the PMN program has resulted not only in the introduction of less hazardous chemicals than would otherwise have been introduced, but also in improvement in the measures taken to limit exposure when new chemicals are introduced.[26]

EPA's Other Authority

SOCMA believes that responsible chemical companies will provide an adequate amount of PMN information and test data for EPA's review. If an individual company does not submit sufficient test data, EPA has ample authority to take regulatory action under section 5(e) to limit or prevent the manufacture of the new chemical. Indeed, the Agency has made use of its section 5(e) authority on a number of occasions to restrict the uses of a new chemical in particular cases where it believed there were insufficient data to evaluate the risks presented by a particular use. Moreover, EPA has the authority to require a new PMN for significant new uses of a chemical and

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26/ Id. at 282.

can track the commercial development of a new chemical through the use of section 8(a) reporting rules.

In light of the general adequacy of the new chemical review mechanism under TSCA, SOCMA believes that there is no need to change the statutory PMN information requirements. The present TSCA system provides appropriate flexibility so that the individual hazard and exposure characteristics of a chemical can be considered in making PMN submissions. We believe that this system is sufficient to prevent unreasonable risks. The imposition of overbroad and inflexible testing requirements, as some have suggested, would unnecessarily impede chemical innovation by small comapnies and thus place their continued existence in jeopardy.

CONCLUSION

In summary, the PMN program has had an adverse and disproportionate impact on innovation by small chemical companies. As a result, there is an urgent need for a workable PMN exemption policy. The Agency should also issue a consistent definition of small business under TSCA. Finally, the new chemical review procedures under TSCA are working and do not need amendment. Implementation of our specific recommendations would reduce the excessive regulatory compliance burden presently borne by small firms and permit them to increase levels of innovation, thus ensuring a stronger chemical industry in the future. At the same time our recommendations are fully consistent with the health and environmental objectives of TSCA.

APPENDIX A

SOCMA MEMBERSHIP

ACETO INDUSTRIAL CHEMICAL CORP.
ALBANY INTERNATIONAL CORP.
AMERICAN CYANAMID CO.
AMERICAN HOECHST CORP.
AMOCO CHEMICAL CORP.
BASF WYANDOTTE CORP.
BERNCOLORS-POUGHKEEPSIE, INC.
BIDDLE SAWYER CORP.
BOFORS NOBEL INC.
BORDEN INC.
BUFFALO COLOR CORP.
CAREY INDUSTRIES, INC.
CARROLL PRODUCTS, INC.
CELANESE CORP.
CHATTEM, INC.
CHEMICAL EXCHANGE INDUSTRIES, INC.
CHEMTAN CO., INC.
CROWN METRO, INC.
DAY-GLO COLOR CORP.
DOW CHEMICAL U.S.A.
DREW CHEMICAL CORP.
E. I. DU PONT DE NEMOURS & CO.
DYE SPECIALTIES, INC.
ESCO - EAST SHORE CHEMICAL CO., INC.
EM INDUSTRIES, INC.
ESSEX CHEMICAL CORP.
EVANS CHEMETICS
FAIRMOUNT CHEMICAL CO., INC.
FIKE CHEMICALS, INC.
FIRST STATE CHEMICAL CO., INC.
FMC CORP.
GAF CORP.
HEXCEL CHEMICAL PRODUCTS
HILTON-DAVIS CHEMICAL CO., THE (GROUP OF STERLING DRUG, INC.)
H & S CHEMICAL, INC.
HUMPHREY CHEMICAL CO., THE
ICI AMERICAS INC.
JARCHEM INDUSTRIES, INC.
KOHNSTAMM, H., & CO., INC.
LOCTITE CORP.
LONZA, INC.
MALLINCKRODT, INC.
MERICHEM CO.
MILLIKEN CHEMICAL (DIV. OF MILLIKEN & CO.)
MOBAY CHEMICAL CORP.
MONSANTO COMPANY
MOONEY CHEMICALS, INC.
MORTON CHEMICAL CO.
MUSKEGON CHEMICAL CO.

NAPP CHEMICALS, INC.
NATIONAL STARCH & CHEMICAL CORP.
OCCIDENTAL CHEMICAL CORP.
OLIN CORP.
C.H. PATRICK & CO., INC.
PENNWALT CORP.
PFISTER CHEMICAL, INC.
PHILLIPS CHEMICAL CO. (A SUB. OF PHILLIPS PETROLEUM CO.)
POLAROID CORP.
PPG INDUSTRIES
PRODUCTS RESEARCH & CHEMICAL CORP.
RSA CORP.
REILLY TAR & CHEMICAL CORP.
RHONE-POULENC, INC.
SALSBURY LABORATORIES
SANDOZ COLORS & CHEMICALS
SAYTECH, INC.
SOLUOL CHEMICAL CO., INC.
STANDARD CHLORINE CHEMICAL CO., INC.
STAUFFER CHEMICAL CO,
STERLING ORGANICS (A DIVISION OF STERLING CHEMICAL GROUP)
SUN CHEMICAL CORP.
SYNALLOY CORP., BLACKMAN UHLER CHEMICAL DIV.
THIOKOL/SPECIALTY CHEMICALS DIV.
UNION CARBIDE CORP.
UPJOHN CO., THE
WHITE CHEMICAL CORP.
WITCO CHEMICAL CORP.
WYCKOFF CHEMICAL CO.

ASSOCIATE MEMBERS

ATLANTA CHEMICAL CO., INC.
BIESTERFELD U.S., INC.
BROWN & CALDWELL
CHEMICAL CONTROL & MANAGEMENT SERVICES, INC.
CHEMISPHERE CORP.
CP CHEMICALS, INC.
DAINICHISEIKA COLOR & CHEMICALS, INC.
ENGELHARD INDUSTRIES
ENVIRONMENTAL RESEARCH & TECHNOLOGY, INC.
FANWOOD CHEMICAL, INC.
R.W. GREEFF & CO., INC.
KENNEDY & KLIM, INC.
HOWARD L. MINCKLER & ASSOCIATES,
MERCANTILE DEVELOPMENT, INC.
MITSUI & CO., (U.S.A.), INC.
MONTEDISON USA, INC.
NACHEM INCORPORATED
ORLEX CHEMICAL CORP.
PYLAM PRODUCTS CO., INC.
R-CHEM, INC.
SPRINGBORN REGULATORY SERVICES, INC.
WILSON DYE & CHEMICAL DISTRIBUTORS, INC.

APPENDIX B

CLEARY, GOTTLIEB, STEEN & HAMILTON

June 1, 1983

MEMORANDUM FOR SOCMA

Re: Small Business Definition Under Section 8(a) Rules

This memorandum sets forth the various definitions of "small manufacturers, importers or processors" used by EPA in various section 8(a) reporting rules under TSCA.

1. Inventory Reporting Rule - In the inventory reporting rule, EPA defined "small manufacturer and processor" as a person whose total annual sales are less than $5 million and who manufactured or imported less than 100,000 pounds of the chemical. 40 C.F.R. § 710.2(x).

2. PBBs and Tris Reporting Rules - In the PBB and Tris reporting rules, EPA defined "small manufacturer or importer" as a person whose total annual sales are less than $500,000 and who manufactured or imported less than 10,000 pounds of PBBs or Tris annually. 40 C.F.R. § 704.195(c)(2)[PBBs], .205(c)(2)[Tris]. These rules were recently recodified in the Code of Federal Regulations under the sections just cited. 48 *Fed. Reg.* 23420 (May 25, 1983).

3. Asbestos Reporting Rule - In the final reporting rule on asbestos, EPA defined "small manufacturer, processor or importer" to be a person who employed no more than 10 full time employees at any one time in 1981. 40 C.F.R. § 763.63(n)(3).

4. Preliminary Assessment Information Reporting Rules - EPA has issued section 8(a) rules requiring preliminary assessment information on almost 300 chemicals, including most test candidates designated by the TITC. *See* 40 C.F.R. § 712.1 - .30; 48 *Fed. Reg.* 22614 (May 19, 1983). The Agency also recently issued an automatic reporting rule for all future test candidates designated by the TITC. 48 *Fed. Reg.* 21294 (May 11, 1983). In these rules, EPA defined "small manufacturer" as a person whose total annual sales revenue at all sites owned or controlled by the foreign or domestic parent company are less than $30 million and who produce less than 100,000 pounds of that chemical at each site. 40 C.F.R. § 712.25(c). However, EPA is presently considering a proposed generic definition of small manufacturer (*See* Point 5 below) and intends to incorporate the finalized generic definition into these preliminary assessment reporting rules. *See* 48 *Fed. Reg.* 21294, 21295 (May 11, 1983).

5. Proposed Generic Definition of Small Manufacturers - In the proposed definition of "small manufacturers" to be generally used in section 8(a) reporting rules, EPA proposed that a manufacturer or importer of chemicals should be considered "small" if: (1) total annual sales of all sites owned or controlled by its foreign or domestic parent company are below $30 million and the manufacturer annually produces less than 45,400 kilograms (100,000 pounds) of a

particular chemical at a particular plant site, or (2) the total annual sales of all sites owned or controlled by the foreign or domestic parent company are less than $3 million regardless of the quantity of chemicals produced by that company. 47 Fed. Reg. 27206 (June 23, 1982). In response to this proposal, SOCMA stated that the sales revenue criteria should be revised so that $40 million in annual sales is used in the first tier and $6,500,000 in annual sales is used in the second tier, and that an automatic annual inflation adjustment mechanism should be adopted.

6. Chlorinated Terphenyl Reporting Rule - In the proposed section 8(a) rule requiring a notice of any current manufacture or import of chlorinated terphenyl, EPA defined "small manufacturer or importer" in the same manner as the proposed generic small business definition. See 48 Fed. Reg. 19419, 19424 (Apr. 29, 1983).

William N. Hall

ENVIRONMENTAL DEFENSE FUND

TESTIMONY OF KHRISTINE L. HALL
AND
DR. ELLEN K. SILBERGELD

ON

THE TOXIC SUBSTANCES CONTROL ACT

BEFORE

THE SUBCOMMITTEE ON TOXIC SUBSTANCES
AND ENVIRONMENTAL OVERSIGHT.
SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE

August 1, 1983

1525 18th Street, N.W. Washington, DC 20036 ☎ 202•833•1484
OFFICES IN: NEW YORK, NY (NATIONAL HEADQUARTERS); WASHINGTON, DC; BERKELEY, CA; DENVER, CO

Mr. Chairman, members of the Subcommittee, my name is Khristine L. Hall. I am an attorney with the Environmental Defense Fund's Toxic Chemical Program. Dr. Ellen Silbergeld, who accompanies me, is the senior toxicologist with EDF's Toxic Chemicals Program. We want to thank you for the opportunity to testify on the Toxic Substances Control Act.

The Environmental Defense Fund is a national nonprofit environmental organization with approximately 47,000 members. Through the combined skills of scientists, economists and attorneys, EDF seeks to insure protection of natural resources and the environment. EDF's Toxic Chemicals Program seeks to minimize or prevent exposure of people and the environment to toxic chemicals. To accomplish that, EDF has worked on enactment and implementation of various regulatory programs concerning toxic substances, including that of the Toxic Substances Control Act.

It is clear that the best way to minimize or prevent harm to people and the environment from toxic substances is to understand the toxicity of such substances and control them before they enter the environment and to act agressively in removing those already in the environment before they become widespread in the environment. These were the purported goals of the Toxic Substance Control Act. In fact, because of deficiencies in the statute and EPA's hesitancy to use their given authority neither of these goals has been met. We urge this Subcommittee to examine closely how the statute is actually functioning in order to determine if its basic goals are being realized.

We would like to endorse the testimony of Jacqueline Warren of the Natural Resources Defense Council on the issue not covered in this testimony.

Lack of Adequate Data

Section 2(b)(1) lists as a basic national policy that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." This is particularly crucial for new chemicals, but has not been fulfilled, largely because of a legislative defect in the Toxic Substances Control Act. Manufacturers of new chemical substances are not explicitly required to develop meaningful toxicity data on new chemicals before they are manufactured. As part of the Pre-Manufacturing Notification (PMN) process, EPA currently requires information only on chemical name and class, production volume, some indication of uses, by-products, worker exposure, and disposal. Conspicuously absent from this list are information on physical-chemical and toxicity data - the very data essential for determining the chemical to human health and the environment. Although, according Section 5(d)(1), when a manufacturer has additional data, he must submit it, and he must submit data on environmental and health effects "insofar as reasonably ascertainable," EPA, has chosen not to interpret this provision to require additional data - even in those cases where such data is "reasonably ascertainable" - i.e. relatively inexpensive to produce.

The result is that EPA must make determinations about the risk to human health and the environment posed by chemicals on little or no relevant information. The recent Office of Technology Assessment background paper, "The Information Content of Premanufacture Notices" documents the fact that EPA receives a pittance of data which it must use to make these important determinations. The paper notes, for instance, that mutagenicity data - data useful in determining whether a chemical is a carcinogen - was submitted in less than 20 percent of the PMNs submitted to EPA so far. Even data for oral acute toxicity - one of the most frequently employed toxicity tests - was submitted only 50 percent of the time. Clearly TSCA has not induced chemical manufacturers to conduct basic toxicity tests and to submit them to EPA.

In the absence of data, EPA has chosen to rely on Structure Activity Relationship analysis (SAR). As traditionally used, SAR analysis is based on molecular similarity to other known chemicals in order to predict the effects of a chemical. Standard SAR analysis is of limited utility for the following reasons:

1. Reliable SAR analysis depends on a comprehensive body of knowledge about the chemcial properties and toxicity risks of existing chemical formulations. Yet it is widely acknowledged that the data base on toxicity of existing chemicals is deficient, even for those few effects -- such as mutagenicity -- which have been widely studied. The data base is particularly deficient for neurotoxicity, reproductive effects, and environmental effects other than lethality. The historical record on failure to use SAR in the prediction of toxicity is embarassing; e.g., the episodes of hexachlorophene and methyl butyl ketone poisoning (ref:

Spencer and Schaumberg, Handbook of Clinical and Experimental Neurotoxicology).

2. Minor alterations in the molecular nature of a chemical, even to the salt or side chain, can cause great changes in its properties, including solubility, metabolism, resistance to hydrolysis, organ distribution, and other factors critically important to toxicity. SAR analysis is simply not able to predict these changes reliably.

SAR analysis may be able to pick out some obvious analogs to known toxins. Its value in exculpating chemicals is unclear. For the vast majority of new chemicals, however, SAR analysis will reveal nothing except the most preliminary estimate of biological properties.

SAR's limitations are well recognized in pharmacology and basic science. In the pharmaceutical industry, SAR can be a preliminary method for initiating the process of evaluating both the potential efficacy and toxicity of new drugs. However, in this industry SAR has not replaced the established methods using experimental animals and/or in vitro systems to determine, with more definition and reliability, the properties of a new compound. This issue has been exhaustively addressed by the

American Society for Pharmacology and Experimental Therapeutics. Likewise, SAR has not been accepted as a substitute for generating toxicity data, limited though it may be, in the pesticides program. There is no logical reason for distinguishing review of new chemicals under TSCA from review of chemicals under these other two federal regulatory programs. Further exacerbating the problem, EPA does not employ standard SAR, which is exemplified by the work of Rodbard and Kauffman. Its own version of SAR, a statistical analysis of similarly toxic compounds is even more deficient in being able to predict chemical properties from past experience, and has not been validated properly.

In short, lack of data has reduced EPA in most instances to making little more than guesses about the risks to health and the environment caused by new chemicals. Thus, the promise held out by TSCA - meaningful review of new chemicals before they cause widespread problems - is not being realized. We strongly recommend that Section 5 of TSCA be amended to mandate that EPA require, as part of the PMN process, submission of a baseline set of toxicology data. Only then can review of new chemicals be truly reviewed in order to avoid unreasonable and preventable risks to human health and the environment.

The situation in the United States concerning lack of data for new chemical review is made even more ridiculous by the fact that a baseline set of toxicity data is required in European Economic Community countries. Although in their infancy, these developing programs raise the distinct possibility that the European data screening process in the Federal Republic of Germany will, for instance, result in restriction on chemicals that can be freely marketed by the same company in the United States. German citizens may be thus afforded better protection than American citizens. The United States is distinctly out of step from other developed chemical-producing countries.

International Cooperation and Harmonization

The experience of European countries points out the worth of international cooperation on toxic chemicals. Indeed, the need for international cooperation and harmonization concerning toxic chemicals has been recognized by the Organization for Economic Cooperation and Development (OECD). The impetus for cooperation in this area grew out of the need to (1) share information about the fate and effect of toxic chemicals; (2) avoid transnational pollution problems; and (3) prevent non-tariff trade barriers arising out of significantly different regulatory programs. OECD's Toxic Chemicals Program has a rather broad agenda including formulation of joint guidelines on testing protocol and data interpretation;

agreement on mutual acceptance of data; and work on exchange of information. Until two years ago, the United States was usually the leader in OECD toxic chemical issues.

One of the most controversial issues of recent years concerned the need for a baseline set of data on new chemicals. Following the European Community's new data requirements, OECD drafted a recommendation that its member countries adopt this baseline set of data, known as Minimum Pre-Market Data (MPD). EPA, in fact, published a policy statement in January, 1981 suggesting that U.S. chemical manufacturers use MPD. In response, American chemical companies started an all out attack on MPD, asserting that TSCA would have to be amended to require such baseline testing. They convinced the Reagan administration to resist vigorously any hint of baseline data requirements. As a result, the United States pushed for a drastic weakening of the OECD recommendation language. During the year and a half of this controversy ran, the United States succeeded in alienating most of its OECD allies and in losing its credibility and position of leadership on matters concerning toxic chemicals. The episode culminated last

November, when OECD countries, all of them very reluctantly, were forced to agree to the MPD language insisted on by the United States. The language is so weak as to be meaningless in harmonizing pre-market screening requirements for chemicals. The United States remains one of the few industrialized countries not to require MPD or its equivalent.

The MPD episode was the low point of U.S. participation in the OECD Toxic Chemicals Program. Since Anne Burford's resignation, there has been evidence of an improved attitude toward these important cooperative efforts. The United States still seems, however, far from resuming its previous leadership efforts.

One important new OECD effort deserves special attention: a project to harmonize efforts to review existing chemicals. U. S. efforts at present in this area are inadequate. We have much to learn from our European and Asian counterparts in reviewing existing chemicals, just as we have much information and many ideas to share with them.

We urge Congress to oversee EPA's participation in OECD toxic chemical activities. These international efforts are important to the success of our own domestic programs and ultimately to the protection of human health and the environment from toxic chemicals.

Non-Carcinogenic Effects

Another serious defect in TSCA and its implementation concerns lack of emphasis on important areas of toxicology. Data on effects on the organ systems of neuropsychiatric function, reproduction, and immune defense are rarely requested by the agency. SAR analysis at its best, is not adequate to evaluate these types of effects. Moreover, in a recent decision, the agency overruled the recommendations of the Interagency Testing Committee (ITC) on an existing chemical which has information available strongly suggesting that it is potentially neurotoxic. The recent decision not to require further toxicity data on pyridine exemplifies this disregard for neurological effects as significant. EPA justified this particular decision on the grounds that the Agency was unaware of any reliable tests for neurotoxicity. At the same time, the EPA is doing little to acquaint itself with the large body of data on neurotoxicity and neurotoxicological test methods (c.f. Mitchell, C. (ed) METHODS IN NEUROTOXICOLOGY, Raven Press, 1981; Spencer and Schaumberg, HANDBOOK OF CLINICAL AND EXPERIMENTAL NEUROTOXICOLOGY, Williams and Wilkins, 1980) or to develop sensitive and reliable methods for establishing the safety of chemicals with respect to the nervous system. In reproductive toxicology, the agency has made some advances in mutagenesis and teratology; however, little is being done to develop test methods or to request information on other parameters of reproductive toxicity -- gonadal effects, hormonal biochemistry, or psychological aspects of sexual function.

Part of the problem stems from the lack of emphasis in TSCA to these important health effects. Section 4, for instance mandates tht EPA and the ITC pay priority attention to chemicals "causing or contributing to cancer, gene mutations, or birth defects." TSCA should be amended to clarify Congress' intent that neurotoxic effects and range of reproduction effects be seriously considered by EPA.

Interaction With Other Statutes

TSCA was passed after many of our other environmental statutes were already in place and was, in fact, intended to fill in the gaps of those other statutes. Unfortunately, it has been so narrowly construed and implemented that it has not met this need.

TSCA could and should play a crucial role in providing information to other programs. A good illustration is the potential relationship between TSCA and the Resource Conservation and Recovery Act (RCRA), the federal statute regulating hazardous waste. Part of the information required in the PMN process regards disposal. Given the unfortunate legacy of past inadequate disposal practices - in particular contaminated groundwater - it makes good sense to review new chemicals to insure that they are properly disposed of and will not create future air, land, or water problems. There is no evidence that a serious review of intended disposal practices is taking place in the TSCA office or, more importantly, that the TSCA and RCRA offices at EPA are coordinating their efforts.

In addition, an important issue in new chemical review is oversight over by-products, as pointed out in the OTA background paper. Yet, according to OTA, 30% of the PMNs contained no information on possible by-products generated during chemical synthesis. Furthermore, EPA does not require information to be submitted on disposal of such by-products. These can be very important toxicologically and environmentally. Dioxin, one of the most potent toxins known, is a by-product in the making of tri- and pentachlorophenols, widely used chemicals. Dioxin has been detected in an alarming number of Superfund sites and industrial locations.

The legislation to reauthorize RCRA recently approved by the Environment and Public Works Committee would set in place a program to ban certain substances from land disposal on the grounds that all landfills will ultimately leak their contents into the environment. The review of all new chemicals and their by-products under TSCA should adopt this approach to determine whether they too should be banned from land disposal.

Likewise, TSCA data on chemicals should be shared with other offices in EPA to insure the most complete understanding of those chemicals that are subject to regulation by other offices. It will make little sense to control the amount of dioxin in a product like 2,4,5 -t- under FIFRA or TSCA, only to permit its release into air and water.

Thank you again for the opportunity to testify. We would be happy to answer any question.

TESTIMONY OF JON GRUNSETH

FIRST VICE CHAIRMAN
BOARD OF DIRECTORS
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON
TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
U. S. SENATE
AUGUST 1, 1983

Chemical Specialties Manufacturers Association
Suite 1120
1001 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 872-8110

TESTIMONY OF JON GRUNSETH
FIRST VICE CHAIRMAN
BOARD OF DIRECTORS
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON
TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
U. S. SENATE
AUGUST 1, 1983

My name is Jon Grunseth. I am First Vice Chairman of the Chemical Specialties Manufacturers Association (CSMA)(located at 1001 Connecticut Avenue, N.W., Washington, D. C.) and Vice-President, Public Affairs, Economics Laboratory, Inc. (St. Paul, Minnesota). I am accompanied today by Mr. Charles Lentz, Director of Health & Environmental Services, Dow Corning Corporation (Midland, Michigan).

CSMA has a membership of nearly 400 firms, many of which are small businesses, engaged in the manufacture, formulation, distribution, and sale of insecticides; disinfectants and sanitizers; detergents and cleaning compounds; automotive chemicals; and waxes, polishes, and floor finishes for household, institutional, and industrial uses. As such, our member companies are subject to EPA jurisdiction pursuant to the requirements of the Toxic Substances Control Act (TSCA).

Mr. Chairman, we welcome the opportunity to provide our comments to your subcommittee on the reauthorization of TSCA.

We respectfully recommend that TSCA be reauthorized for two or more years without change or modification, and that the careful balance initially constructed be retained. Although the statute may not be perfect, the law is working and industry is striving hard to achieve its objectives. The statute should be given an opportunity to be fully implemented.

We also believe it would be most appropriate for the new EPA Administrator to have sufficient time to review the Agency's priorities and to review TSCA and the toxic substances programs.

TSCA must be viewed in light of its unique role in the matrix of health and environmental statutes. When evaluated from this perspective, any revisions in TSCA at this time would upset the present balance and unnecessarily disrupt and delay its maturing process. Alteration of one part of TSCA would distort the integrated approach that Congress achieved when the law was enacted. Therefore, CSMA advocates no legislative changes in TSCA at this time.

TSCA was enacted in 1976 and implementation began January 1, 1977. This legislation is unique among the numerous health and environmental statutes in its breadth, scope and purpose. Enacted after many previous environmental laws, TSCA was essentially designed to provide environmental protection in areas not addressed by other statutes. In writing this legislation, Congress perceived that TSCA should have the broadest and most flexible authority so that it could require everything from labeling to the banning of a substance. In establishing TSCA, Congress created a different system than those under such statutes as FIFRA and the Food, Drug & Cosmetic Act (FDCA). I would like to take just a moment to review the comparative legislative history of these environmental, health and safety statutes.

FIFRA was designed to regulate the sale and use of pesticides. Many of these pesticides were recognized as economic poisons designed to kill pests, and their use is restricted because of this potential. Congress knew in advance that it was dealing with potentially toxic products, and established a registration and approval system.

Under the Food, Drug and Cosmetic Act, Congress again recognized that it was dealing with a unique group of compounds such as food and drugs which have direct human exposure, and recognized the impact that these compounds might have on man and the environment. To deal with these concerns, Congress established an extensive NDA approval system requiring premarket testing and clearance.

Under TSCA, however, Congress initiated the broadest possible program directed at the full range of chemicals and gave the EPA an extensive scope of powers not found under other statutes. Due to the breadth of this statute, Congress created a pre-manufacture notification system. Throughout the legislation, Congress sought to create a delicate balance that would evaluate risks and benefits, and would "consider the environmental, economic and social impact of any action the Administrator takes or proposes to take under this Act." (Section 2(c) -- Intent of Congress)

Congress gave the EPA broad powers to review new chemical substances before their commercial manufacture. TSCA also provides authority for requiring testing and information gathering on existing chemical substances and gives the EPA broad authority to regulate the manufacture, processing, distribution, and disposal of new and existing chemicals. This authority was essentially designed to fill the gaps created by other existing statutes. To avoid overlapping regulations, Congress intended that the EPA would invoke TSCA to control existing chemicals only where a substance presented "an unreasonable risk of injury to health or the environment" or created an "imminent hazard" not adequately addressed under other health and environmental statutes such as FIFRA, FDCA, Internal Revenue Code (firearms and ammunition), Federal Meat Inspection

Act, Eggs Products Inspection, Poultry Products Inspection Acts, and laws governing tobacco and tobacco products. Because of the important and often essential role of chemicals and innovation in maintaining economic growth, TSCA also directs the EPA to avoid requirements that would "unduly impede technological innovation."

TSCA is necessarily an intricate law with many interlocking provisions; its implementation has also been a complex process. Nevertheless, after six years, there is unmistakable evidence that the law is working and that government and industry are moving toward the unique purposes of TSCA. Since the law's enactment, the EPA has devoted approximately $350 million to its TSCA program and has taken major strides to implement each of TSCA's major provisions.

TSCA's impact on industry has been widespread and significant, and important changes in industry practices have accompanied TSCA's implementation. For example, substantial resources have been required to interpret and comply with the EPA requirements, to collect data and file reports, to prepare PMNs and other required submissions, and to develop, implement and monitor testing programs. TSCA Sections 4, 5, 6 and 8 regulations in particular have placed significant burdens on industry.

In the initial period following the TSCA's enactment, the EPA was faced with the difficult task of interpreting the complex requirements of the law, building a functioning staff and organization, and developing a workable approach to TSCA's principal provisions in light of the diversity of substances to be covered. TSCA programs generated considerable controversy as the Agency proposed a number of regulations that were scientifically unsound, legally questionable, impractical, and unduly burdensome. These

DIFFICULTIES ARE BEING ADDRESSED, HOWEVER, AND AS A RESULT, THE EPA'S PRESENT TSCA PROGRAMS, WHILE NOT SATISFACTORY IN ALL RESPECTS, ARE RESULTING IN TANGIBLE PROGRESS IN ACHIEVING THE ACT'S OBJECTIVES OF PROTECTING HUMAN HEALTH AND THE ENVIRONMENT.

TSCA ESTABLISHES COMPREHENSIVE PROGRAMS FOR INFORMATION-GATHERING, TESTING AND CONTROL OF UNREASONABLE RISKS. U. S. INDUSTRY HAS EXTENSIVE VOLUNTARY RISK CONTROL PRACTICES. IN VIEW OF THE STRINGENT REGULATORY AND NON-REGULATORY SAFEGUARDS THAT ARE ALREADY IN PLACE IN THE UNITED STATES, CAREFUL ADMINISTRATION OF TSCA IS NECESSARY TO AVOID MAKING U. S. INDUSTRY LESS COMPETITIVE IN WORLD MARKETS.

ALTHOUGH WE ARE NOT SEEKING ANY MODIFICATIONS OF THE TSCA STATUTE, WE WOULD LIKE TO TAKE THIS OPPORTUNITY TO DISCUSS, BASED ON OUR EXPERIENCE, SOME OF THE CONCERNS WE HAVE WITH THE IMPLEMENTATION OF TSCA. OPERATING WITHIN THE CURRENT STATUTORY FRAMEWORK, WE ARE HOPEFUL THAT THESE CONCERNS CAN BE ADDRESSED BY WORKING WITH THE ADMINISTRATION, THROUGH THE REGULATORY PROCESS.

SECTION 5 REQUIREMENTS

DURING THE LAST SIX YEARS, THE SECTION 5 PROVISIONS OF TSCA HAVE LED TO THE IMPLEMENTATION OF A PREMANUFACTURE NOTIFICATION (PMN) PROCESS AND A SYSTEM OF EVALUATING NEW CHEMICALS. WHEN TSCA WAS ENACTED IN 1976, CONGRESS AVOIDED THE IMPOSITION OF SPECIFIC TESTING REQUIREMENTS UNDER SECTION 5 FOR VERY GOOD REASONS. MANDATORY TESTING REQUIREMENTS WOULD:

1) BE TOO RIGID AND PROVIDE TOO LITTLE FLEXIBILITY IN EXERCISING SCIENTIFIC JUDGMENTS;
2) RESULT IN INAPPROPRIATE AND UNNECESSARY TESTING;
3) LEAD TO SIGNIFICANT DELAYS IN PROCESSING THE AVAILABLE DATA AND IMPLEMENTING THE PROGRAM;

4) NOT DISTINGUISH BETWEEN THOSE NEW CHEMICALS THAT NEED SUBSTANTIAL TESTING AND THOSE NEW CHEMICALS WHICH ARE MINOR MODIFICATIONS OF EXISTING CHEMICALS WHICH HAVE BEEN WIDELY USED AND STUDIED EXTENSIVELY, AND THEREFORE NEED MINIMAL TESTING;

5) NOT SEPARATE THOSE CHEMICALS THAT HAVE A HIGH RISK POTENTIAL FROM THOSE THAT ARE LOW RISK, SUCH AS THOSE CHEMICALS THAT ARE UNLIKELY TO HAVE SIGNIFICANT EXPOSURE BECAUSE THEIR PRODUCTION VOLUME IS LOW OR BECAUSE THEY WILL BE MANUFACTURED AND USED UNDER HIGHLY CONTROLLED CONDITIONS; AND

6) SEVERLY INHIBIT INNOVATION IN THE CHEMICAL INDUSTRY, ESPECIALLY AMONG SMALLER COMPANIES.

TSCA'S PMN REQUIREMENTS HAVE BEEN GENERALLY FUNCTIONING EFFECTIVELY FOR OVER THREE YEARS. THE EUROPEAN ECONOMIC COMMUNITY'S SIXTH AMENDMENT WHICH RELIES ON PREMARKETING DATA, HAS BEEN OFFERED BY SOME AS THE JUSTIFICATION FOR "BASE SET" TESTING. IN CONTRAST TO THE TSCA PMN PROCESS, THIS EEC PLAN HAS NOT YET BEEN FULLY IMPLEMENTED. FEW, IF ANY, PREMARKETING NOTICES CONTAINING THE RESULTS OF "BASE SET" TESTING HAVE TO DATE BEEN SUBMITTED TO EUROPEAN NATIONAL AUTHORITIES. IT WOULD BE UNWARRANTED AND COUNTERPRODUCTIVE FOR THE UNITED STATES TO ABANDON A REGULATORY SYSTEM THAT HAS DEMONSTRATED EFFECTIVENESS IN FAVOR OF AN UNPROVEN ACROSS-THE-BOARD "BASE SET" APPROACH.

THE PMN PROCESS: SECTION 5 OF TSCA REQUIRES THE EPA TO REVIEW THE HEALTH AND ENVIRONMENTAL EFFECTS OF ALL "NEW" CHEMICALS BEFORE THEIR COMMERCIAL INTRODUCTION. TO PERMIT SUCH REVIEW, A PMN DESCRIBING THE CHEMICAL, ITS ANTICIPATED USES, ALL AVAILABLE HEALTH AND SAFETY DATA, AND CERTAIN OTHER SPECIFIED INFORMATION

MUST BE SUBMITTED TO THE EPA AT LEAST 90 DAYS BEFORE THE START OF PRODUCTION. UNDER CONDITIONS SPECIFIED IN SECTION 5(E), THE EPA CAN DELAY OR PREVENT THE MANUFACTURE OR USE OF A NEW CHEMICAL PENDING THE DEVELOPMENT OF TEST DATA OR OTHER INFORMATION. ALSO, SECTION 5(F) AUTHORIZES THE EPA TO RESTRICT MANUFACTURE OR USE WHERE, IN THEIR VIEW, A NEW CHEMICAL PRESENTS AN UNREASONABLE RISK OF INJURY.

AFTER A CHEMICAL COMPLETES PMN REVIEW, TSCA PROVIDES THE EPA WITH WIDE-RANGING AUTHORITY FOR MONITORING AND CONTROLLING THE CHEMICAL THROUGHOUT ITS COMMERCIAL LIFE CYCLE. PRODUCTION, USE, AND HEALTH AND SAFETY DATA CAN BE COLLECTED UNDER SECTION 8; TESTING CAN BE REQUIRED UNDER SECTION 4; AND CONTROL MEASURES CAN BE IMPOSED UNDER THE SIGNIFICANT NEW USE PROVISIONS OF SECTION 5, THE RULEMAKING PROVISIONS OF SECTION 6, OR THE IMMINENT HAZARDS PROVISIONS OF SECTION 7.

THE EPA HAS FOUND THAT THE GREAT MAJORITY OF NEW CHEMICALS IT REVIEWS RAISE MINIMAL HEALTH OR ENVIRONMENTAL CONCERNS AND CAN ENTER THE MARKETPLACE WITHOUT RESTRICTION. THESE OBSERVATIONS ARE CONFIRMED BY THE FACT THAT, BY THE EPA'S ESTIMATE, APPROXIMATELY 50 PERCENT OF ALL PMNS HAVE COMPLETED REVIEW WITHIN 15 DAYS AFTER THEIR SUBMISSION AND ALL BUT A HANDFUL OF THE REMAINING PMNS HAVE COMPLETED REVIEW WITHIN 45 DAYS. WE BELIEVE THAT WHEN THE REVIEW IS COMPLETED IN LESS THAN 90 DAYS, THE EPA ADMINISTRATOR SHOULD BE ABLE, UNDER THE STATUTE, TO ALLOW THE PRODUCTION OF THE MATERIAL AS SOON AS IT HAS ITS REVIEW COMPLETED.

IN ADDITION, THERE HAVE BEEN SOME SITUATIONS WHERE PRODUCTS ARE NEEDED IMMEDIATELY, AND SHOULD BE MADE AVAILABLE AFTER A SHORT REVIEW PERIOD AS PROPOSED FOR SUBSTANCES EXEMPTED UNDER SECTION 5(H)(4). WE BELIEVE THE EPA ADMINISTRATOR SHOULD ACT IN THESE SITUations to allow rapid production of a much-needed product. We also believe that the PMN exemptions under section 5(h)(4) should be administratively established for polymers, small volume chemicals (under 10,000 kg./year), and site-limited intermediates, as EPA has proposed.

The EPA has taken prompt action on those few occasions where a new chemical raises sufficient health or environmental concerns to warrant control. To date, the EPA has issued orders under section 5(e) prohibiting production of or otherwise regulating 18 new chemicals pending the development of test data. PMNs for several other new chemicals have been withdrawn in the face of likely EPA action. Moreover, in numerous instances, PMN submitters have cooperated in addressing the EPA's concerns about new chemicals. In approximately 60 cases, manufacturers have volunteered to suspend the PMN review period while developing additional data or, at the EPA's request, have instituted measures to reduce exposure or otherwise limit risks from PMN chemicals. These statistics confirm that a high percentage of the chemicals that enter the PMN process pose low risks and that the process is effectively identifying those few new chemicals that warrant closer attention.

Although the PMN process appears to be working and has protected human health and the environment, it has not fulfilled the TSCA mandate in section 2(b)(3). This section provides that TSCA "should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation . . . ." Many small businesses have incurred problems with the PMN process, but I will comment on this later in my statement.

Testing of New Chemicals: Section 5(b)(2)(B) creates important incentives to assure that adequate data on such chemicals are available

BEFORE MANUFACTURE. IF A PMN LACKS SUFFICIENT INFORMATION TO PERMIT A REASONED EVALUATION OF THE NEW CHEMICAL'S HEALTH OR ENVIRONMENTAL EFFECTS, THE EPA MAY PROHIBIT OR LIMIT MANUFACTURE OF THE CHEMICAL WHERE IT: 1) MAY PRESENT AN UNREASONABLE RISK; OR 2) WILL HAVE SUBSTANTIAL PRODUCTION VOLUME AND SIGNIFICANT ENVIRONMENTAL RELEASE OR HUMAN EXPOSURE. IN ORDER TO AVOID A SECTION 5(E) ORDER, TO PROHIBIT OR LIMIT MANUFACTURE, PROCESSING OR DISTRIBUTION, IT IS IN THE PMN SUBMITTER'S INTEREST TO IDENTIFY AND DEVELOP THE INFORMATION NEEDED FOR A REASONED EVALUATION OF THE NEW CHEMICAL'S HEALTH AND ENVIRONMENTAL EFFECTS. IF SUCH INFORMATION IS OMITTED FROM THE PMN AND A SECTION 5(E) ORDER IS ISSUED, MANUFACTURE WILL BE SUSPENDED UNTIL THE NECESSARY DATA ARE DEVELOPED AND SUBMITTED FOR THE EPA'S REVIEW.

TO DATE, THE EPA HAS USED ITS SECTION 5(E) AUTHORITY SPARINGLY. FOR NEARLY ALL NEW CHEMICALS, THE INFORMATION CONTAINED IN THE PMN OR SUPPLIED VOLUNTARILY BY THE MANUFACTURER, COMBINED WITH THE EPA'S IN-HOUSE EXPERTISE, HAS BEEN SUFFICIENT FOR A MEANINGFUL RISK ASSESSMENT.

SECTION 4 TEST RULES

IMPORTANCE OF NEGOTIATED TESTING: COOPERATIVE ACTION BY THE EPA AND INDUSTRY HAS PLAYED AN INCREASINGLY IMPORTANT ROLE IN ACHIEVING SECTION 4'S TESTING OBJECTIVES, AND HAS EXPEDITED THE GENERATION OF DATA.

NEGOTIATED AGREEMENTS REPRESENT A WRITTEN, PUBLIC COMMITMENT BY INDUSTRY TO CONDUCT TESTING. THE EPA RETAINS ITS RULEMAKING AUTHORITY TO COMPEL TESTING AND STOP PRODUCTION IN THE UNLIKELY EVENT THAT INDUSTRY FAILS TO ADHERE TO A NEGOTIATED AGREEMENT. FAILURE TO HONOR SUCH COMMITMENTS TO CONDUCT TESTING WOULD DETRACT FROM INDUSTRY'S CREDIBILITY AND JEOPARDIZE ITS RELATIONSHIP WITH THE EPA, ITS CUSTOMERS

AND THE PUBLIC. ACCORDINGLY, INDUSTRY HAS IMPORTANT INCENTIVES TO ENSURE THAT NEGOTIATED TESTING PROGRAMS ARE FULLY PERFORMED.

USE OF INDUSTRY LABORATORIES FOR TESTING PURPOSES: SOME CRITICS OF INDUSTRY TESTING HAVE SUGGESTED THAT IN ADDITION TO ITS OWN REVIEW THE EPA SHOULD REQUIRE THAT INDEPENDENT OR GOVERNMENT LABORATORIES TO DEVELOP OR REVIEW ALL DATA SUBMITTED UNDER TSCA. WE BELIEVE THIS SUGGESTION IS INAPPROPRIATE.

INDUSTRY LABORATORIES ARE AMONG THE VERY BEST IN THE WORLD AND HAVE SOME OF THE MOST HIGHLY-ACCLAIMED RESEARCH SCIENTISTS. THE RECORD INDICATES THAT INDUSTRY HAS DONE AN EXCELLENT JOB OF TESTING AND HAS ESTABLISHED THE HIGHEST QUALITY OF RESEARCH.

A FOOD AND DRUG ADMINISTRATION STUDY (1969-1970) OF LABORATORIES AROUND THE NATION CONCLUDED THAT THE HIGHEST QUALITY OF RESEARCH WAS CONDUCTED IN INDUSTRY LABORATORIES WHEN COMPARED TO INDEPENDENT AND UNIVERSITY AND GOVERNMENT LABORATORIES. THIS STUDY DOCUMENTS THE QUALITY OF INDUSTRY LABORATORIES AND REINFORCES THE CREDIBILITY OF INDUSTRY TESTING. WE ARE CERTAINLY WILLING TO EXPLORE ALL AVENUES BY WHICH WE MIGHT IMPROVE THE TESTING PROCEDURES OF INDUSTRY LABORATORIES, BUT WE STRONGLY OPPOSE ANY CHANGE IN THE PRESENT SYSTEM OF REVIEW OF DATA SUBMITTED UNDER TSCA.

TSCA CONTAINS COMPREHENSIVE AUTHORITY TO REQUIRE THE TESTING OF EXISTING CHEMICALS AND THE EPA IS NOW EXERCISING THAT AUTHORITY EFFECTIVELY. SIMULTANEOUSLY, THE UNITED STATES CHEMICAL INDUSTRY HAS CONTINUED TO PLACE A SUBSTANTIAL EMPHASIS ON VOLUNTARY HEALTH AND ENVIRONMENTAL TESTING. AS A RESULT, IMPRESSIVE PROGRESS IS BEING MADE IN ACHIEVING TSCA'S OBJECTIVE OF ESTABLISHING A SOUND DATA BASE ON THE HEALTH AND ENVIRONMENTAL EFFECTS OF EXISTING CHEMICALS.

IMPURITIES

THE EPA SHOULD FOLLOW THE ADVICE OF CONGRESS WHEN IT ADDRESSED THE QUESTION OF IMPURITIES IN THE CONFERENCE COMMITTEE. "THUS THE DEFINITION OF THE TERM 'CHEMICAL SUBSTANCE' SHALL BE APPLIED TO CHEMICAL SUBSTANCES AS ACTUALLY PRODUCED AND MARKETED." (LIBRARY OF CONGRESS, ENVIRONMENTAL AND NATURAL RESOURCES POLICY DIVISION, LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT (WASHINGTON, D. C.: U.S. GOVERNMENT PRINTING OFFICE, DECEMBER, 1976), P. 670.) IT IS IMPORTANT FOR THE EPA TO RECOGNIZE THAT A GENERIC POLICY ON IMPURITIES IS INAPPROPRIATE BUT RATHER EVALUATIONS ON A CASE-BY-CASE BASIS IS THE ONLY SENSIBLE WAY TO APPROACH THIS COMPLEX ISSUE. THIS ALLOWS FOR REGULATING THE SUBSTANCE AND THE LEVEL OF IMPURITY INTENTIONALLY OR INADVERTENTLY IN THE SUBSTANCE BUT DOES NOT PROVIDE FOR REGULATING THAT SAME PURITY IN ALL OTHER UNNAMED OR UNIDENTIFIED SUBSTANCES. WITHOUT THIS APPROACH THE IMPURITIES (A CHEMICAL SUBSTANCE INADVERTENTLY PRESENT AS A COMPONENT OF A SEPARATE CHEMICAL) QUESTION COULD IN FACT CONFUSE OR RETARD THE COMPLIANCE AND ENFORCEMENT OF THE LAW IN SECTIONS 4, 5, 6, 7, 8, 12, AND 13. THE EPA CAN STILL ASSESS AND CONTROL REAL RISKS BY REGULATING THE LEVEL OF IMPURITIES IN SPECIFIC PRODUCTS WITHOUT TRYING TO COVER ALL POSSIBLE SITUATIONS IN ONE RULE, A PROCESS WASTEFUL OF EPA'S LIMITED RESOURCES.

CONCERNS MORE UNIQUE TO SMALL BUSINESSES

I WOULD LIKE TO RESPECTFULLY URGE YOUR SUBCOMMITTEE TO INITIATE A COMPLETE EXAMINATION OF THE PROBLEMS SMALL BUSINESSES FACE IN COMPLYING WITH TSCA. THE IMPLEMENTATION OF TSCA WILL CONTINUE TO HAVE A SIGNIFICANTLY DISPROPORTIONATE IMPACT ON SMALL BUSINESSES, ESPECIALLY THE SMALL CHEMICAL MANUFACTURER. WE ALSO BELIEVE THAT THE SUBCOMMITTEE OUGHT TO ENCOURAGE THE EPA TO EXAMINE THE METHODS AND MEANS TO MINIMIZE

ADMINISTRATIVE BURDENS AND TO INCREASE THE UNDERSTANDING OF THE PROBLEMS THAT SMALL BUSINESSES HAVE IN COMPLYING WITH TSCA. IN ADDITION, WE RESPECTFULLY URGE THE SUBCOMMITTEE TO ENCOURAGE THE EPA TO EXAMINE TSCA REGARDING THE INTERESTS AND CONCERNS OF SMALL COMPANIES AND TAKE INTO ACCOUNT THE DIFFERENCES IN ABILITY TO COMPLY BETWEEN LARGE AND SMALL FIRMS.

THERE IS A SERIOUS NEED TO ELIMINATE THE INCONSISTENT, UNNECESSARY AND BURDENSOME REQUIREMENTS FOR SMALL BUSINESSES BY ENSURING CONSIDERATION OF SMALL BUSINESS INTERESTS INITIALLY, RATHER THAN AS AN AFTERTHOUGHT.

THE PROVISIONS OF TSCA HAVE RESTRICTED THE ABILITY OF SMALL CHEMICAL COMPANIES TO TAKE ADVANTAGE OF THEIR SPECIAL CAPACITY FOR INNOVATION AND QUICK RESPONSE TO IMMEDIATE AND SPECIALIZED NEEDS OF CUSTOMERS, WHICH HAS BEEN AN IMPORTANT BASIS FOR SMALL COMPANY COMPETITIVENESS. CUSTOMARILY, SMALL CHEMICAL COMPANIES HAVE ALSO MAINTAINED THEIR COMPETITIVE PRICING IN THE MARKETPLACE AS A RESULT OF MINIMAL OVERHEAD COSTS AND LOWER PROFIT MARGINS. TSCA HAS DISRUPTED SMALL COMPANY COMPETITIVENESS BY IMPOSING SUBSTANTIAL FIXED COSTS RELATED TO PMN SUBMISSION, DATA GENERATION, RECORDKEEPING AND REPORTING. WE WOULD LIKE TO FOCUS OUR ATTENTION ON THREE DIFFICULT PROBLEMS UNDER TSCA: 1) THE TSCA IMPACT ON INNOVATION BY SMALL BUSINESS; 2) THE TSCA REPORTING AND RECORDKEEPING REQUIREMENTS FOR SMALL BUSINESSES; AND 3) THE DEFINITION OF SMALL BUSINESS.

INNOVATION: TO ADDRESS THE IMPACT OF TSCA ON INNOVATION WITHIN THE CHEMICAL INDUSTRY, THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION COMMISSIONED THE REGULATORY RESEARCH SERVICE, (A PART OF KIRCHNER ASSOCIATES INC.), AN INDEPENDENT CONSULTING FIRM, TO CONDUCT A COMPREHENSIVE ANALYSIS OF THE ACT'S EFFECT ON THE CHEMICAL SPECIALTIES

INDUSTRY. THE STUDY WAS UNDERTAKEN BECAUSE OF CSMA'S CONCERN THAT TSCA WAS HAVING A SERIOUS ADVERSE IMPACT ON DEVELOPMENT OF NEW PRODUCTS AND SUBSTANCES BY MEMBER FIRMS. IT'S GOAL WAS TO PROVIDE BOTH A QUANTITATIVE ASSESSMENT OF THE IMPACT ON INNOVATION WITHIN THE INDUSTRY TO DATE, AND BUILD A BASELINE OF DATA FOR FUTURE EVALUATION. MR. CHAIRMAN, WE WOULD LIKE TO SUBMIT A COPY OF THIS STUDY FOR THE HEARING RECORD.

ONE HUNDRED MEMBER FIRMS PROVIDED DATA FOR THE STUDY WHICH COVERS THE FIVE YEAR PERIOD FROM 1976 TO 1981. SEPARATE ANALYSES WERE CONDUCTED FOR CHEMICAL INGREDIENT SUPPLIERS AND END-USE PRODUCT MANUFACTURERS. THE RESULTS OF THE STUDY INDICATE THAT A MAJOR IMPACT OF TSCA HAS BEEN DUE TO ITS REQUIREMENT IN EFFECT SINCE 1978 THAT FIRMS FILE A NOTIFICATION WITH THE EPA 90 DAYS BEFORE THE MANUFACTURE OF ANY NEW CHEMICAL SUBSTANCE. SPECIFICALLY, THE STUDY SHOWED THAT:

- TSCA HAS RESULTED IN A DECLINE OF MORE THAN 25 PERCENT IN NEW SUBSTANCE DEVELOPMENT WITHIN THE CHEMICAL SPECIALTIES INDUSTRY. SMALLER BUSINESSES ARE MOST SEVERELY AFFECTED, ESPECIALLY THOSE WITH LESS THAN $50 MILLION IN SALES (A DECLINE OF 85-95 PERCENT).
- MUCH OF THE DECLINE IN CHEMICAL SPECIALTIES INNOVATION IS DIRECTLY ATTRIBUTABLE TO THE COST OF FILING THE TSCA-REQUIRED PRE-MANUFACTURING NOTICE (PMN).
- COSTS FOR FILING PMNS FAR EXCEED SIMPLY THE TIME CONSUMED IN PAPERWORK. OTHER FACTORS INCLUDE DELAYS IN MANUFACTURE, AND UNCERTAINTY IN KNOWING HOW TO FILE AND WHAT INFORMATION IS REQUIRED, WITH THE IMPACT AGAIN PARTICULARLY STRONG ON SMALL FIRMS WHICH HAVE LIMITED REGULATORY RESOURCES AND EXPERTISE.

- TSCA could have serious future impacts on innovation in the chemical specialties industry, with very significant rates of innovation decline projected for small firms. Present PMN filing costs could cause about 30 percent of CSMA's membership to cancel between 12 and 49 percent of their plans for new product development, with smaller manufacturers again most heavily affected.

The CSMA study also indicated potential for several long-term impacts on the chemical specialties industry should the "innovation rejection trend" continue. These include increased failure of small businesses, serious lessening of competition, and a loss of economic productivity and social benefits due to a decrease in innovation.

In summary, the impact of TSCA on ingredient suppliers appears to demonstrate the innovation rates are lower and will continue to be lower until:

- Direct costs of PMN filing are substantially reduced;
- Firms are better informed about the type and quantity of information necessary for a PMN submission;
- EPA develops PMN exemption procedures for low risk chemicals (i.e. site limited intermediates, polymers of known monomers, and low volume chemicals) under TSCA section 5(h)(4);
- EPA simplifies the PMN filing process to reduce costs;
- EPA recognizes the existence of a commercial practice, that customers now frequently require PMNs before they will accept new chemicals for evaluation or for test marketing and make allowances for this factor in the PMN process.

REPORTING AND RECORDKEEPING REQUIREMENTS: ALTHOUGH LOSS OF INNOVATION IS A SIGNIFICANT PROBLEM FOR SMALL MANUFACTURERS, THE EXISTING BURDENS OF REPORTING AND RECORDKEEPING UNDER SECTION 8 OF TSCA ALSO HAVE A DISPROPORTIONATE IMPACT ON SMALL BUSINESSES. IT IS POSSIBLE TO REDUCE THESE REQUIREMENTS WITHOUT JEOPARDIZING THE INFORMATION NEEDED TO MAKE A FAIR RISK ANALYSIS.

A SIGNIFICANT NUMBER OF SMALL MANUFACTURERS OF CHEMICAL SUBSTANCES ARE VITALLY INTERESTED IN THE PARAMETERS USED BY THE EPA TO EXEMPT SMALL CHEMICAL MANUFACTURERS FROM MOST OF THE FUTURE REPORTING AND RECORDKEEPING RULES ISSUED UNDER SECTION 8(A) OF TSCA. THE GATHERING OF RISK-RELATED INFORMATION ON CHEMICALS SHOULD NOT STRAIN THE LIMITED FINANCIAL AND PERSONNEL RESOURCES OF SMALL COMPANIES UNLESS IT IS ABSOLUTELY NECESSARY FOR THE PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT.

THE CONGRESSIONAL INTENT, AS WELL AS THE LEGISLATIVE HISTORY, IS VERY CLEAR. THE CONGRESSIONAL DEBATE OVER TSCA INDICATES AN UNDERSTANDING THAT SMALL COMPANIES HAVE FEWER ADMINISTRATIVE PERSONNEL AND LESS CAPABILITY FOR DATA COMPILATION AND STORAGE THAN LARGER FIRMS. THE SMALL COMPANIES TEND TO BE LESS AUTOMATED AND MORE LABOR INTENSIVE, WITH PROPORTIONALLY FEWER RESOURCES DEVOTED TO MANAGEMENT ACTIVITIES, INCLUDING REGULATORY COMPLIANCE. IN EXPLAINING THE SECTION 8(A) EXEMPTION LANGUAGE, THE HOUSE REPORT STATES THAT, "BECAUSE REPORTING AND RECORDKEEPING REQUIREMENTS UNDER SECTION 8(A) MAY IMPOSE A PARTICULARLY HEAVY BURDEN ON SMALL MANUFACTURERS OR PROCESSORS, THE COMMITTEE PROVIDES AN EXEMPTION FROM SUCH REPORTING AND RECORDKEEPING FOR SMALL MANUFACTURERS OR PROCESSORS," H. REP. 94-1341, 94TH CONG. 2D SESS. 42-43 (1976).

WE WOULD ALSO URGE THE SUBCOMMITTEE TO EXAMINE THE RECORDKEEPING PROVISIONS FOR SMALL BUSINESSES. THE PRESENT RECORDKEEPING

REGULATIONS OUGHT TO BE EXAMINED TO SEE IF THEY CAN BE SIGNIFICANTLY MODIFIED TO REDUCE THE EXCESSIVELY BURDENSOME, UNFAIR, AND UNPRODUCTIVE REQUIREMENTS.

DEFINITION OF SMALL BUSINESS: DESPITE THE CLARITY OF THE LEGISLATIVE HISTORY, ENVIRONMENTAL LAWS, SUCH AS TSCA, DO NOT HAVE A UNIFORM DEFINITION OF SMALL BUSINESS.

SMALL COMPANIES GENERALLY HAVE CHEMICAL SALES OF LESS THAN $40 MILLION (1983 DOLLARS) OR EMPLOY 30 OR FEWER EMPLOYEES. SMALL BUSINESSES FREQUENTLY LACK THE LARGE TECHNICAL STAFF AVAILABLE TO LARGE COMPANIES TO GATHER OR GENERATE EXTENSIVE ENVIRONMENTAL INFORMATION AND TOXICOLOGICAL DATA. THEY ALSO LACK THE ADMINISTRATIVE CAPABILITY TO HANDLE EXTENSIVE REPORTING AND RECORDING REQUIREMENTS, LARGELY BECAUSE THEY ARE LABOR-INTENSIVE BUSINESSES THAT CANNOT AFFORD TO DEVOTE UNNECESSARY, DUPLICATIVE MANAGEMENT ACTIVITY TO THESE TASKS.

EPA ACTIONS TO LIMIT BURDENS FOR SMALL BUSINESSES: AS CONGRESS RECOGNIZED IN PASSING THE REGULATORY FLEXIBILITY ACT (RFA) IN 1980, SMALL BUSINESSES HAVE LONG SHOULDERED THE SAME BURDEN OF FEDERAL REGULATIONS AS THEIR LARGER COMPETITORS, BUT WITH FEWER RESOURCES. UNIFORM REGULATIONS WHICH DO NOT TAKE INTO ACCOUNT THE SIZE OF THE REGULATED BUSINESSES IMPOSE SUBSTANTIAL FIXED COSTS ON SMALL COMPANIES WHICH THEY CANNOT AS EASILY ABSORB DUE TO LOWER SALES VOLUMES AND LIMITED STAFF.

THE RFA REQUIRES AGENCIES TO ANALYZE HOW EACH REGULATION WILL AFFECT THE ABILITY OF SMALL ENTITIES TO INVENT, TO PRODUCE AND COMPETE. UNDER ITS PROVISIONS, AGENCIES MUST BALANCE THE BURDENS IMPOSED BY REGULATIONS AGAINST THEIR BENEFITS AND PROPOSE ALTERNATIVES TO REGULATIONS WHICH WOULD CREATE ECONOMIC DISPARITIES BETWEEN DIFFERENT-SIZED ENTITIES. THE PRINCIPLES OF THE RFA MUST BE FOREMOST IN THE MINDS OF

THE EPA REGULATORS WHEN IMPLEMENTING TSCA TO ENSURE THAT THE REGULATIONS ARE RATIONAL, NECESSARY AND CONSTRUCTED IN A MANNER THAT DOES NOT OVERLY TAX THE SCARCE RESOURCES OF SMALL BUSINESSES.

RECENTLY, THE EPA HAS TAKEN SEVERAL COMMENDABLE MEASURES WHICH ADDRESS SMALL BUSINESS PROBLEMS UNDER VARIOUS TSCA REQUIREMENTS. THESE ACTIONS HAVE INCLUDED THE APPOINTMENT OF A SMALL BUSINESS OMBUDSMAN IN EPA'S OFFICE OF MANAGEMENT AND POLICY REVIEW, THE ISSUANCE OF A PROPOSED SMALL BUSINESS EXEMPTION FOR MORE REPORTING AND RECORDKEEPING RULES UNDER SECTION 8(A), AND PROPOSED PMN EXEMPTIONS FOR POLYMERS, LOW-VOLUME CHEMICALS AND SITE-LIMITED INTERMEDIATES.

IN ADDITION, THE TSCA ASSISTANCE OFFICE PROVIDED MUCH-NEEDED AID IN UNDERSTANDING AND COMPLYING WITH THE REQUIREMENTS OF TSCA. SEVERAL OF OUR MEMBERS HAVE USED THE PMN FIELD TECHNICAL SERVICE TO SMALL BUSINESS, WHICH ENABLED THEM TO SUCCESSFULLY FILE PMNS. MANY OF THE SMALLER FIRMS WHO DEPEND ON THIS TECHNICAL SUPPORT TO COMPLY WITH TSCA REQUIREMENTS WOULD BE PLACED AT GREAT DISADVANTAGE WITHOUT IT.

CSMA STRONGLY URGES YOU TO CONTINUE TO SUPPORT THE ACTIVITIES OF THE TSCA ASSISTANCE OFFICE. CSMA AND ITS MEMBER COMPANIES ALSO WISH TO EXPRESS OUR APPRECIATION OF THEIR WORK AND OUR COMMITMENT TO WORK WITH THE EPA TOWARD OUR COMMON GOAL OF A BETTER ENVIRONMENT.

WHILE THERE HAS THUS BEEN PROGRESS ON SEVERAL MATTERS OF CONCERN TO SMALL BUSINESS, MORE NEEDS TO BE DONE IF SMALL CHEMICAL COMPANIES ARE TO CONTINUE AS VIABLE MEMBERS OF THE CHEMICAL INDUSTRY. WE HOPE THAT SOME OF THE OTHER PREVIOUSLY MENTIONED CONCERNS WITH TSCA CAN BE RESOLVED BY WORKING WITH THE ADMINISTRATION.

SCIENTIFIC PEER REVIEW

IN 1975, THE CONGRESS CREATED A SCIENTIFIC ADVISORY PANEL FOR

THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA), AND IT HAS WORKED WELL. ITS ACTIVITIES HAVE BEEN APPLAUDED BY ALL INTERESTED PARTIES. AS CHANGES WERE MADE OVER THE YEARS, IT HAS EVOLVED INTO AN EFFECTIVE INSTRUMENT FOR DETERMINING SCIENTIFIC ACCURACY AND HAS ESTABLISHED A RECOGNIZED SYSTEM OF SCIENTIFIC PEER REVIEW. IN ESSENCE, THE VERY EXISTENCE OF A PANEL HAS HELPED TO MAKE THE AGENCY'S DECISIONS MORE RESPONSIBLE AND RESPONSIVE TO SCIENTIFIC KNOWLEDGE.

WE AT CSMA BELIEVE THAT DECISIONS UNDER TSCA SHOULD BE MADE ON THE BEST AVAILABLE SCIENTIFIC DATA, SO THAT THE PUBLIC'S HEALTH AND THE ENVIRONMENT CAN BE PROTECTED. WE FEEL THAT THE EPA SHOULD ESTABLISH A SIMILAR INDEPENDENT SCIENTIFIC REVIEW PANEL UNDER TSCA TO ADDRESS SCIENTIFIC MATTERS.

THE ESTABLISHMENT OF SUCH A PANEL WOULD CREATE A SCIENTIFIC PEER REVIEW PROCESS THAT WOULD INTERJECT VALID SCIENTIFIC INFORMATION INTO THE DECISION-MAKING PROCESS AT THE EPA. IT COULD REVIEW HEALTH AND SAFETY DATA, AS WELL AS PROTOCOLS AND PROPOSED TESTING REQUIREMENTS. THE PURPOSE OF A PANEL WOULD BE TO REVIEW THE SCIENCE, BUT NOT THE POLICY DECISIONS UNDER TSCA. THE PANEL COULD CONDUCT ITS DELIBERATIONS IN AN OPEN AND ACCESSIBLE FASHION SO THAT THE PUBLIC AND INDUSTRY COULD MAKE COMMENTS AS NECESSARY.

SUCH A SCIENTIFIC ADVISORY PANEL COULD MAKE A MAJOR CONTRIBUTION TO THE SCIENTIFIC DEFENSIBILITY OF DECISIONS UNDER TSCA.

TSCA: FEDERAL-STATE RELATIONSHIP

ONE OF THE MOST IMPORTANT PROBLEMS THAT OUR INDUSTRY FACES IS THE POTENTIAL INCONSISTENCY IN STATE LAWS. AS WE APPROACH THE MID-1980S, WE ARE GOING TO BE DISCUSSING REVENUE-SHARING, THE NEW FEDERALISM AND THE QUESTION OF FEDERAL-STATE RELATIONSHIPS. UNDER TSCA, THIS PROBLEM MAY BE FREQUENTLY RAISED.

THERE ARE IMPORTANT PRECEDENTS IN OTHER STATUTES THAT HAVE ESTABLISHED FEDERAL PREEMPTION OF STATE AND LOCAL GOVERNMENT ACTIVITIES. UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT, THE NATIONAL TRAFFIC AND MOTOR VEHICLE SAFETY ACT OF 1966 AND THE CONSUMER PRODUCT SAFETY ACT, STATUTORY LANGUAGE HAS ESTABLISHED A PRECEDENT FOR FEDERAL PREEMPTION.

WE AT CSMA BELIEVE THAT STATE GOVERNMENTS AND POLITICAL SUBDIVISIONS OF A STATE SHOULD BE PROHIBITED FROM ENACTING TSCA-TYPE LEGISLATION. IF ANYTHING, WE NEED TO IMPROVE THE USE OF INFORMATION BY STATES, RATHER THAN EXPANDING THEIR AUTHORITY.

THERE IS NO NEED FOR STATE OR LOCAL GOVERNMENTS TO REQUIRE DATA, INFORMATION, OR RECORDKEEPING AT THEIR LEVEL. SUCH STATE EFFORTS WOULD RESULT IN COSTLY DUPLICATION OF RESOURCES WITHOUT EITHER INCREASING THE AMOUNT OF AVAILABLE INFORMATION OR REDUCING THE RISK OF CHEMICAL SUBSTANCES.

IN CONCLUSION, WE SHARE A COMMON GOAL THAT OUR PRODUCTS ARE SAFE AND EFFECTIVE FOR THEIR INTENDED USES AND THAT THESE MATERIALS DO NOT POSE UNREASONABLE RISKS TO MAN AND HIS ENVIRONMENT. CSMA REMAINS COMMITTED TO MAKING TSCA AN EFFECTIVE LAW TO PROMOTE HUMAN HEALTH, SAFETY AND THE ENVIRONMENT.

IN THE PREVIOUS SIX YEARS UNDER TSCA, WE BELIEVE THAT CONSIDERABLE PROGRESS HAS BEEN MADE IN IMPLEMENTING THE LAW. ALTHOUGH WE HAVE SOME PROBLEMS AND CONCERNS WITH THE STATUTE, WE RESPECTFULLY URGE THIS SUBCOMMITTEE TO REAUTHORIZE TSCA FOR TWO OR MORE YEARS WITHOUT CHANGE OR MODIFICATION. WE HOPE THAT WE CAN ADDRESS SOME OF OUR CONCERNS BY WORKING WITH THE ADMINISTRATION THROUGH THE REGULATORY PROCESS. CSMA WILL CONTINUE TO WORK WITH THIS SUBCOMMITTEE IN ANY WAY THAT WE CAN TO CREATE AN EFFECTIVE TSCA PROGRAM.

AGAIN, THANK YOU, MR. CHAIRMAN, FOR THIS OPPORTUNITY TO ADDRESS OUR CONCERNS AND TO PROVIDE OUR VIEWS TO YOUR SUBCOMMITTEE. WE WOULD BE PLEASED TO ANSWER ANY QUESTIONS YOU OR YOUR SUBCOMMITTEE MEMBERS MAY HAVE.

IMPACT OF THE TOXIC SUBSTANCES CONTROL ACT ON INNOVATION IN THE CHEMICAL SPECIALTIES MANUFACTURING INDUSTRY

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION
1001 Connecticut Avenue, N.W.
Suite 1120
Washington, D.[illegible]36

[Note: The following has been excerpted from the above named report. The complete report has been retained in the committee files.]

[redacted]

EXECUTIVE SUMMARY

In 1981 the Chemical Specialties Manufacturers Association (CSMA) undertook a formal study of the impact of the Toxic Substances Control Act (TSCA) on its membership. The study covered the years 1976-81. Its purpose was twofold: (1) to determine what impact TSCA had already had on the development of new ingredients and new products by member firms; and (2) to develop and prepare a baseline for measurement and evaluation of future impacts.

The study was limited to the 198 member firms who were identified as either ingredient suppliers or product manufacturers. Member firms who were less directly impacted (e.g. testing laboratories, hardware component suppliers, etc.) were not asked to participate. To obtain as complete and representative a body of data as possible, two separate data collection approaches were employed: (1) a formal mail survey questionnaire sent to the entire relevant membership; and (2) in-depth field interviews with 50 member firms selected at random. The study consisted of a total sample of 100 firms--50 responding to the mail questionnaire only; 31 providing only field interviews; and 19 providing both mail questionnaire and field interview responses. Of the 69 total firms responding to the mail questionnaire, 42 were product manufacturers; 22 were ingredient suppliers; and 5 were firms in both categories. The 31 additional firms who were interviewed reflected the same relative composition. The survey sample was determined to be statistically representative of the relevant membership.

The survey was designed to obtain three types of data: (1) economic background and profile data on the firm and its participation in chemical specialties manufacturing; (2) a five-year data series on the commercial practices, perceptions, and attitudes of firms in the development of new substances and products before and after TSCA implementation; and (3) data on firms' rationale for undertaking or rejecting innovation. All data were provided under a strict confidentiality agreement negotiated with CSMA, which prohibited disclosure of specific firm data.

Because their market structure and regulatory problems differ significantly, separate analyses were conducted for ingredient suppliers and product manufacturers. Findings were made in three areas: (1) changes in number and type of innovations before and after TSCA; (2) behavioral factors influencing innovation; and (3) assessment of the economic impact of regulatory costs on innovation.

Number and Type of Innovation

For ingredient suppliers, a substantial decline in innovation activity appears to have occurred since 1979. This was the first year of the implementation of TSCA pre-manufacturing notification (PMN) regulatory requirements. However, the impact of TSCA on this decline cannot be fully separated from other causes. New substance development on the average was 26 percent lower for 1979-81, than it was for a comparable (pre-implementation) 1976-78 period. The decline has been experienced almost entirely by the smaller ingredient suppliers with sales under $100 million, rather than by the larger firms. Of the observed decline in innovation for 18 ingredient suppliers reporting useable data between 1976-78 and 1979-80, the 12 firms under $100 million in sales accounted for 98 percent of the total decline. These smaller firms were found in many instances, to depend much more heavily for their continued sales upon new products and ingredients than were their larger counterparts. Firms below $200 million in specialties sales depend three times more heavily on sales of substances not in existence five years ago than do larger firms.

For the most part, the innovation decline appears to have taken the form of a reduction in the more risky types of innovation; i.e., those developed for a firm's general market, rather than those presumably less risky activities initiated in response to customer requests. The decline in innovations undertaken primarily to serve the general market was 38 percent between the 1976-78 and 1979-81 periods; the decline in those undertaken at customer request was only 14 percent.

Product manufacturers, on the other hand, have not yet experienced significant impact in terms of number or types of innovations. Regulations that will probably most affect them--Significant New Use rules under TSCA Section 5 (a) (2)--have not yet been proposed by EPA. Thus, for manufacturers, the innovation data obtained constitute a baseline for future assessment. Innovation activity for manufacturers occurs most commonly for re-formulation and new formulation of current products, rather than for introduction of completely new products.

Factors Affecting Innovation Activity

For ingredient suppliers, two regulatory factors were identified which influence the apparent declining rate of innovation activity. These are:

- o The increasingly common commercial practice of the customers of ingredient suppliers in requiring that a PMN be completed before they will accept a new substance for testing and evaluation, even though TSCA does not require such a notice.

- o Firms' misperception and uncertainty as to how much and what type of data, especially toxicity testing data, EPA requires to process a PMN. This lack of understanding was most noted for firms with little or no experience in the PMN filing process, who tended almost uniformly to be the smaller firms in the specialties sector.

These factors, added to the direct cost of filing a PMN, create regulatory cost burdens in the minds of many firms which are quite substantial relative to the investment return expected from new substance commercialization, and thus considerably dampen the incentive to innovate. This was particularly the case for smaller firms; i.e., those below $200 million in annual sales.

Both product manufacturers and ingredient suppliers are motivated to innovate primarily for cost-reduction or other standard commercial reasons. Although some experts have asserted that health and safety regulatory requirements in themselves will create substantial positive incentives to innovate, this study found evidence that such factors are not a significant primary motivating force.

Economic Significance of Innovation Impact

Based on innovation profit expectations data provided by ingredient supplier firms, a predicted rate of innovation decline based on realistic levels of TSCA regulatory cost was calculated for each firm in the survey, using realistic assumptions about such regulatory costs developed from both the survey and independent studies. Declines in the rates of projected innovation as a result of TSCA costs were on the whole substantial, and were particularly heavy for firms in smaller size classes. Ingredient suppliers under $100 million in total annual specialties sales would reject, on the average, almost half of potential ingredient innovations if faced with realistic PMN cost levels estimated to be between $16,000 and $18,000. Rates for the smallest size class of firms, i.e. those under $10 million, were even higher. Rejection rates fall off sharply for larger firms (i.e. over $200 million in sales), but the dollar levels of rejected innovation are still substantial for them. Even though PMN filing costs are assumed to be up to 37 percent lower for smaller ingredient suppliers (i.e. those below $100 million in overall annual sales), these firms on the average would have an almost 50 times greater probability of rejecting, for PMN cost reasons, a planned innovation that otherwise met their minimum profit expectations, than would their larger counterpart firms (i.e. above $200 million). These predicted patterns of innovation decline were strongly confirmed by independent data obtained from these firms in the survey as to actual pre- and post-TSCA patterns of innovation, and attitudes toward innovation behavior as a result of TSCA.

Generally similar rejection rates were determined for product manufacturers, should they be faced with approximately the same levels of TSCA costs in the future, once Significant New Use and other rules are in effect.

Generalizing results for the CSMA membership as a whole, one finds that a substantial portion of CSMA member firms would experience significant rates of innovation decline at realistically assumed levels of TSCA regulatory cost. About 30 percent of member ingredient manufacturers would experience between a 12 and 49 percent rate of decline for ingredient innovation. In addition, 20 percent of the product manufacturer members would experience a similar decline in innovation if confronted with the same levels of regulatory costs.

It was not possible in this initial study formally to assess long-term impacts and causes of foregone innovation, although initial survey results indicate the strong potential for several long-term impacts. These could include: (1) possible business failure, particularly of smaller ingredient suppliers, since they depend more heavily than do their larger counterparts upon new substances for their continued existence; (2) lessening of competition; and (3) loss of social benefits and economic productivity, which can be expressed both as lost opportunities for large-scale technological break-throughs, and loss of significant benefits to the consuming public and to the industry at large.

Economic Methodology Used

The economic impact assessment findings of the study were based upon a methodology that treated innovation as an investment decision, to which the methodology of return-on-investment decision-making applied. Survey results showed that specialties firms undertake new substance, product, or process development primarily for traditional economic and commercial investment reasons. A firm thus can be regarded as deciding whether to innovate or not by making a pre-investment judgment that the lifetime profitability of a particular innovative activity (after deducting all capital and operating costs) will or will not meet or exceed its minimum dollar target profit goals. Regulatory costs of TSCA then become a cause for rejection by a firm of an innovation that it would otherwise undertake, when these costs become substantial enough to force anticipated profits below the firm's minimum acceptable target goals. Thus, knowledge of the firm's targets of minimum profit acceptability in the absence of TSCA, together with realistically specified levels of TSCA regulatory costs, defined the basic methodological framework used.

Detailed data about planning target investment goals were reported by firms for 38 ingredient lines. However, relatively fewer meaningful responses were provided by firms reporting profit targets in the higher ranges. These firms tended generally to be larger firms. Specific findings on innovation impact of TSCA for such firms must be interpreted with correspondingly more caution than results for smaller CSMA members.

* * *

Overall, the study has resulted in the creation of a significant five-year pre- and post-TSCA baseline making it possible: (1) to track the impact on innovation of any other actual or potential TSCA cost; (2) to study the impact on both large and small members of the chemical specialties sector; and (3) to begin to assess more specifically longer term social and economic impacts.

SUMMARY AND CONCLUSIONS

A. INTRODUCTION

The objective of this study has been to assess the impact of the Toxic Substances Control Act on innovation in the chemical specialties industry, and to prepare a baseline for measurement and evaluation of impacts in the future. The study was conducted by means of a mail survey to all members of the Chemical Specialties Manufacturers Association (CSMA) who were ingredient suppliers or specialties product manufacturers, and interviews with key officials in 50 of these firms.

The survey sample consisted of a total of 100 firms: 50 who responded to a mail questionnaire only; 31 who provided only field interviews; and 19 who provided both mail questionnaire and field interview responses. Of the 69 firms who responded to the mail questionnaire, 42 were product manufacturers; 22 were ingredient suppliers; and five were firms reporting in both categories. The 31 additional firms who were interviewed in depth reflected the same relative composition. The survey sample was determined to be statistically representative of the relevant membership as a whole.

B. TRENDS IN NEW PRODUCT DEVELOPMENT

1. Ingredient Suppliers

Ingredient suppliers have produced 26 percent fewer new substances since 1979 than they produced in the 1976-1978 time period. Moreover, it is significant that the impact has been largely on smaller firms. The reduction has come mostly in the area of firm-supported speculative research and development, and there is now a higher proportion of R&D activity devoted to responding to customer-requested research activity. In 1980, 94 percent of the research projects discontinued were speculative development activities of firms. Ingredient suppliers, especially smaller firms, are reducing their risk-taking and may be becoming reactive rather than active innovators.

The involvement of TSCA in this process seems to be indicated by the decline in new substance innovations since the TSCA PMN requirement became effective, although the impact of TSCA on this decline cannot be fully separated from other causes.

There are several factors which seem to have influenced the reduced level of innovation. First is the substantial cost impact associated with the commercial practice of requiring completion of the PMN process before a customer will accept a new chemical substance for evaluation and product testing, even though the law does not require PMNs for this category of chemical. The data show that a firm can expect to encounter this practice 49 times out of 100 when sending out sample material. This practice adds an economic cost of $6,100 per PMN. Given the direct cost of completion of EPA's current forms for filing PMNs (industry average cost of $7,500), the added economic cost of EPA's requirement for PMNs on captive intermediates ($2,400), and the expected failure rate of items sent out for customer test and evaluation (56 percent), the equivalent average economic cost burden on a firm for a PMN filing on a commercially successful material becomes

$16,000. It is expected that all other factors being equal, this cost could soon increase to $22,000 as the rate for the commercial practice of requiring an advance PMN approaches 100 percent. This cost is exclusive of any costs for incremental toxicity tests, or any indirect costs of the PMN process such as delay and uncertainty. These latter costs are particularly likely to impact smaller firms with less experience in and fewer resources to cope with the regulatory process.

Second is the apparent wide misperception in the industry that health and safety testing is required before EPA will process a PMN. Interviews with suppliers indicated that this misperception may be fostered by EPA, as EPA staff have routinely urged PMN filers to submit health and safety data. Neither the law nor EPA regulations requires a firm to perform any testing prior to filing or to having EPA process a PMN. EPA completed a statistical analysis on all PMN filings*/ in 1979 and 1980 which shows that in 1979 and 1980, 67 and 66 percent respectively of all PMNs submitted contained no toxicity data, and EPA processed them. If EPA believes there is evidence a new substance could present unreasonable risks, testing can be required under TSCA Section 5(e), and commercial production can be delayed. EPA initiated Section 5(e) orders on only six PMN submissions out of 361 filings in 1980. A 5(e) order cannot be issued without cause, and is open to court challenge.

The survey data, confirmed in company interviews, indicate that 72 percent of ingredient supplier firms who were intending not to file a PMN in

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*/Status of Pre-manufacture notices, EPA internal report, January 29, 1981.

1981, or would file fewer PMNs in the future, felt that the "testing cost of filing" was of first importance in determining this intention. If a firm believes that testing must be performed before a PMN can be filed, then the negative impact on innovation is understandable, since testing is expensive. Initial toxicity screening can cost $3,000 to $5,000, and a full battery of toxicity testing can cost $500,000 and more. These costs are in addition to the PMN filing costs described above.

The commercial practice of firms' requiring an advance PMN, given the misperception that testing is required to file a PMN, aggravates an already bad situation. Since firms know that at least half of the items developed and sent out for customer evaluation will end up as commercial failures, they correctly perceive that much of the testing expense may be wasted. EPA's resources are also wasted. There is therefore a great need to correct industry misperceptions regarding advance filing requirements for PMNs.

The industry interviews indicated a general agreement that toxicity testing of new substances is necessary in many instances where there is a potential for human environmental exposure. It is primarily the timing of such testing that is at issue. Firms felt they should not be in the position of expending large sums for toxicity testing before it is determined that there is a commercial interest in the material. In the tradition of the industry prior to TSCA, toxicity testing was conducted if necessary as a commercial interest developed. These expenditures were seen as appropriate because they were applied only to ventures with a high probability of success. Moreover, testing was coordinated with both the extent and nature of the intended use. Testing for the sole purpose of obtaining a PMN in the absence of any perceived need arising from human or environmental exposure or known commercial interest is certain to waste potentially large amounts of resources.

EPA's interest in toxicity testing for PMN chemicals can be seen, however, as making sense in terms of the original conceptual framework of TSCA. R&D materials are exempt from the PMN process, and a manufacturer in filing a PMN must attest to the fact that the firm intends to go into production. EPA therefore may erroneously believe that only materials which will reach commercial production are having PMNs filed, leading to EPA's advocacy of toxicity testing for all PMN substances. Given the current commercial practice of requiring an advance PMN 49 percent of the time, combined with the 56 percent failure rate on new substances sent out for customer evaluation, 27 out of 100 PMNs which EPA is receiving are for substances which will most probably not be produced; in the future this could increase to 56 out of 100 PMNs filed.

Third, firms have a misconception about the type and quantity of data EPA requires in order to process a PMN, beyond that arising from the testing issue described above. EPA has processed letter-style PMNs submitted to them. Firms have spent as little as $224 and as much as $45,000 on unchallenged PMN filing, exclusive of toxicity testing. As indicated above, the industry average filing cost is about $7,500, in terms of average level of effort expended, given the widespread use of the October 16, 1979 version of EPA's PMN form. Filing costs certainly appear to be able to be reduced.

In summary, some impact of TSCA on ingredient suppliers appears to have been demonstrated. Innovation rates are lower and, according to industry members interviewed and surveyed, will continue to be lower until:

- o Direct costs of PMN filing are substantially reduced
- o Firms understand that toxicity testing is not necessary to obtain a PMN
- o Firms are better informed about the type and quantity of data necessary to include in a PMN submission
- o EPA develops PMN exemption procedures for low risk chemicals (i.e. captive intermediates, polymers of known monomers, and small volume chemicals) under TSCA section 5(h)(4)
- o EPA simplifies the PMN filing process to reduce costs
- o EPA recognizes the existence of the commercial practice of customers requiring advance PMNs and makes allowance for this factor in the PMN process.

It is believed, however, by many surveyed firms that the commercial practice of customers requesting a PMN in advance of accepting a substance for evaluation and product testing would be difficult if not impossible to change. It is human nature to seek certainty whenever possible. Consequently, firms may be reluctant to expend resources on evaluation and product testing until EPA "passes on" a PMN. A confounding influence here is that the economic loss associated with the negative impact of advance PMN requirements always has the appearance of being borne by the supplier firm -- in the short run. In the long run, product manufacturers may also suffer as the supply of new materials may be significantly reduced.

2. Specialties Product Manufacturers

One principal purpose of the survey of product manufacturers was to obtain information which could be used to evaluate EPA's Significant New Use rulemaking under TSCA Section 5(a)(2). Product manufacturers, by definition in this study, do not produce new chemical substances; therefore, they can have experienced little or no direct impact on innovation from the PMN process. The product manufacturers also do not report other major TSCA impacts at this time.

Most importantly, the survey has provided a significant data baseline for the period 1976-81 against which the impact of SNURs and other TSCA regulations can be measured in the future.

Product manufacturers average 4-5 new products per year. New products contain original formulations developed by the manufacturer 57 percent of the time. About 17 percent of these products contain chemical substances which the manufacturer believes constitute the first use of such a substance in the given product application. About one-third of these "first use" substances are new chemical substances. Therefore, about 3.4 percent of original formulations contain new chemical substances.

Product manufacturers average three changes in formulations of old (current) products each year. One-third of these formulation changes involve the use of chemical substances which the firm believes constitutes the first use of such substances in the product application. Only about 6 percent of these "first-use" substances are new chemical substances.

Therefore, about 2 percent of these re-formulations contain new chemical substances.

The largest amount of innovative activity for product manufacturers is in their existing product lines. There is much more frequent first-use of a chemical substance as well as greater use of new substances in these current products, than there is by firms in development of new products.

It may be speculated that the number of new substances reported by product manufacturers as used in their products and formulations may be lower than the number actually used. It seems possible, based on field interviews, that some product formulators may not always be aware that chemical substances which they are using for reformulation are new at the time they are evaluating the applicability of such substances. More new substances may therefore be involved in new formulations than were reported in the survey.

The survey has canvassed the reasons product manufacturers undertake new product development and re-formulate old products. Currently, these firms develop the majority of new products for customary commercial reasons; non-commercial reasons such as health and safety and regulatory pressure constitute only about 8 percent of the total reasons offered. Re-formulations are undertaken primarily to reduce costs, and this factor has increased as a motivator from 10 percent of total reasons offered in 1976 to 45 percent in 1981. Data on old (current) products show that health, safety, and regulatory factors declined in importance as motivating factors for formulation innovation during the five year base line period. This does not infer, however, that concern in general for health and safety is declining, but only that it is declining as a primary reason for reformulation.

As expected, reasons for discontinuance by firms of development projects show little influence of TSCA; rather, firms primarily indicate normal commercial reasons. Discontinuances for reasons of potential adverse health and safety regulatory activity, or appearance of an ingredient on a hazard suspect list, together account for only about 6 percent of all reasons given.

C. IMPACT OF REGULATORY COST ON INNOVATION

The impact of regulation on chemical specialities firm innovation was examined by: (1) determining the nature of firms' innovation investment plans in the absence of regulation; (2) estimating the impact of realistic hypotheses concerning TSCA regulatory costs on these innovation plans; and (3) comparing these estimates where possible with firms' actual estimates and assessments of what TSCA impact has actually been. Results were then generalized to the CSMA membership as a whole and long-term implications assessed, to the extent possible.

Since assessment in terms of traditional economic investment models using rate-of-return on investment (ROI) data did not prove feasible, (firms having regarded these data as competitively sensitive), an alternative, closely related method was employed that was both consistent with traditional investment theory and in addition satisfied firms' perceived needs for confidentiality of business information. The method employed was:

(1) to ask firms to provide data on minimum dollar levels of target profit needed by them to undertake innovation investments in the absence of regulation; and then (2) to investigate how specified levels of regulatory costs would impact those minimum profit targets. Depending upon the size and time distribution of such profits, and the magnitude of regulatory costs, TSCA causes a certain proportion of innovations to fall below minimum target levels and thus be rejected. Such rejection rates were then calculated and compared with firms' actual behavior, and the results generalized and assessed for long-term implications.

Using this general methodology, ingredient suppliers and product manufacturers were investigated separately, since each is subject to a different set of regulatory requirements and competitive influences.

1. Impact of TSCA Regulation on Ingredient Supplier Innovation

Rejection rates for potential innovation investment were estimated for the sample of 27 ingredient suppliers providing relevant minimum target profit data. Firms ranged in size between under $10 million in annual sales to those over $500 million, and were generally representative of the composition of CSMA membership. A minimum and maximum cost estimate was then provided for costs related to the PMN rule, which is the major regulatory requirement of TSCA that affects ingredient suppliers. This PMN cost estimate was based on previous empirical findings. In addition, based on judgmental assessment of survey data and related evidence from field interviews, firms were assumed to be able to transfer 20 percent of their regulatory costs forward to product manufacturers and other users.

Principal findings were as follows:

(a) Based on firm interviews and survey questionnaire data, it was found that firms would reject a significant percentage of the time, innovations that they would previously undertaken in the absence of TSCA PMN costs.

(b) At a $4,000 assumed lower limit of regulatory costs, small ingredient suppliers (under $10 million in sales) would reject for PMN cost reasons up to 23 percent of the new substance innovations that they would otherwise have undertaken. For higher, more realistic levels of TSCA regulatory costs, this proportion increases significantly, until it reaches 70 percent potential rejection at levels of PMN cost between $15,000 and $18,000 dollars.

(c) The impact of PMN costs falls almost entirely, and heavily, on smaller firms, mostly producing ingredients in smaller sales size classes, with lower minimum target profit levels per innovation. Even though filing costs are assumed to be up to 37 percent lower for smaller firms (i.e., those below $100 million in overall sales), these smaller firms would on the average have an almost fifty times greater probability of rejecting an innovation for PMN cost reasons than would firms in larger overall size classes (above $200 million).

assessing innovation impact. Some firms are derivative manufacturers or formulators who undertake activities primarily in response to competitive pressure. The respondent sample was adjusted to eliminate firms not in the relevant universe. Otherwise, the innovation analysis for product manufacturers employed the same basic assumptions and procedures which were used for ingredient supplier assessment. Based on CSMA survey data, similar levels of TSCA regulatory costs were assumed.

Principal findings from this analysis were as follows:

(a) Innovation rejection by firms will be substantial, again concentrated heavily and almost exclusively in smaller size firms.

(b) At upper-bound estimates of TSCA regulatory cost of $15-18 thousand small firms surveyed (under $10 million in total specialties sales) would reject between 66 and 69 percent of potential innovations. Firms manufacturing products under $1 million in total annual sales would reject innovation activity approximately 86 percent of the time. At lower-bound regulatory cost estimates between $4 thousand and $6.4 thousand, rejection rates fall but are still substantial. Firms under $10 million in total specialties product sales would reject innovation 29 to 40 percent of the time, and firms making products with under $1 million in annual sales in a specialties product line, would reject innovation activities 49 to 60 percent of the time.

(d) The subtantial impact on firms' innovation plans of estimated regulatory costs was corroborated by empirical survey data on firms' actual impact experience.

(e) PMN costs have apparently had substantial impact on the innovation activity of a significant portion of CSMA member firms as a whole. Almost 30 percent of all member firms of less than $100 million in total ingredient specialties sales would, on the basis of this survey and analysis, be projected to experience between a 16 and 49 percent decline in innovation investment activity that would otherwise be undertaken but for PMN costs.

(f) The long-run impact of these changes on firms' financial health is potentially substantial, and made more so by the fact that, according to the survey, most small ingredient supplier firms (under $200 million in overall firm sales), are much more heavily dependent on recurrent innovation for their sales (and perhaps profits) than are their larger counterparts.

2. Impact of TSCA Regulation on Product Manufacturer Innovation

The analysis conducted of TSCA regulatory impact on product manufacturers and formulators differs from that for ingredient suppliers for two reasons: (1) major regulatory costs in the form of a Significant New Use Rule (SNUR) and other TSCA rules have not yet been put in place for any chemical specialty ingredients, even on a proposed basis; and (2) not all manufacturers are in the universe of potential innovators for purposes of

(c) Compared with large firms, it appears, based on analysis of survey findings, that firms with total product specialties sales under $10 million are at least thirty times more likely on the average to reject a projected innovation at a given level of regulatory costs than would firms between $100 and $200 million in such sales, and at least 200 times more likely to reject planned innovation than are firms in the size class above $200 million. Findings for firms in larger size classes must be interpreted with considerable caution, however, because of the small and possibly unrepresentative nature of the sample.

(d) The substantial predicted impact on firms' innovation plans of projected regulatory costs was to some extent corroborated by limited data from field interviews with large and small product manufacturers.

(e) A significant proportion of CSMA product manufacturers could be impacted by TSCA regulatory costs, i.e. those in the smaller size classes. More than twenty percent of members could experience between a 36 and 67 percent decline in product and formula innovation as a result of minimum and maximum TSCA costs between $4,000 and $18,000, respectively. Generalizations for larger firms cannot be made as readily because of the small number of firms in the sample.

3. Long-term Implications and General Conclusions

(a) The reduced innovation activity observed heavily and mainly in the small business group of the specialties sector as a result of TSCA can impose large costs on society as a whole. Product innovation is enormously important to commercial success in the chemical industry and has tended, according to previous studies, to be relatively evenly distributed among large and small firms. To the extent that small firms shoulder the majority of the burden of decline in innovation, a substantial loss of competition can be expected to be felt over time through business shifts to larger firms. Losses in productivity will also result, and could be substantial, since the benefits from a particular innovation are not confined solely to the originating firm but rather are passed along as well to customers and to competing firms which may imitate the original innovation or use it as a basis for improvement. One study, for example, based on a limited number of chemical industry innovations,*/ found that the social rate of return on innovation (counting the added benefits to customers and competitors) was more than twice the private rate of return for the firm alone. An additional significant aspect of the predicted loss of firm innovation observed in this survey arises from the fact that many important applications of an innovation may not become apparent until the product or process has been in use for many years. Thus, many of the small innovations that initially appear to be of modest value, and therefore choked off by the cost of a SNUR, PMN, or other TSCA rule, might ultimately have produced great social benefits. Many important chemical products have exhibited such a pattern in the past, and limited evidence from specialties experience supports this conclusion. Some indication of the importance of these factors has been provided in the survey. About three-fourths of ingredient suppliers and product manufacturers indicated that they have either shelved newly created products temporarily or permanently, and/or postponed development as a result of TSCA regulation. Fifty-six percent of ingredient suppliers and fifty percent of the manufacturers sampled indicated they had restricted sales to certain markets to avoid TSCA requirements, and/or decided to remain with an old product when they were confident a better one could have been produced. Although the significance of these results could not be determined in a specific product context, they clearly indicate the potential for substantial economic loss to the public beyond private losses to the firms in question.

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*/Mansfield, E., et. al., The Production and Application of New Industrial Technology, pp. 144-158.

(b) A significant five-year pre- and post-TSCA baseline has been obtained which will be useful in evaluating innovation impact in the future. Existence of such a baseline will enable CSMA, in subsequent follow-up phases of this effort, to trace the changing number and importance of new products as a result of TSCA regulation, especially in regard to the differential impacts on small versus large firms; to assess more specifically the impact of SNURs and other TSCA rules when such rules are forthcoming from EPA; and to provide more definitive experience with PMNs when a rule is finalized.

OVERSIGHT HEARINGS ON THE TOXIC SUBSTANCES CONTROL ACT (P.L.94-469)

SENATE COMMITTEE ON THE ENVIRONMENT

SENATE COMMITTEE ON THE ENVIRONMENT AND PUBLIC WORKS

ROOM 406-DIRKSEN OFFICE BUILDING

10 A.M., AUGUST 1, 1983

TESIMONY OF THE AMERICAN PUBLIC HEALTH ASSOCIATION
1015, 15TH STREET NORTHWEST, WASHINGTON, DC. 20005, (202)789-5600

BY

ALLEN N. KOPLIN, MD, MPH.
ACTING COMMISSIONER OF HEALTH, STATE OF NEW JERSEY
DEPARTMENT OF HEALTH, JOHN FITCH WAY,
TRENTON, NEW JERSEY 08625 (609)292-7873

CHAIRMAN DURENBERGER AND MEMBRES OF THE COMMITTEE:

THANK YOU FOR THE OPPORTUNITY TO APPEAR TODAY TO PRESENT THE TESTIMONY OF THE AMERICAN PUBLIC HEALTH ASSOCIATION ON THE TOXIC SUBSTANCES CONTROL ACT (PL94-469). THE APHA REPRESENTING 50,000 PUBLIC HEALTH WORKERS THROUGHOUT THE NATION HAS A CRITICAL STAKE IN THE IDENTIFICATION AND CONTROL OF TOXIC SUBSTANCES IN THE HUMAN ENVIRONMENT. IT IS OUR PARTICULAR CONCERN THAT THE CHEMICAL PRODUCTS TO WHICH WE ARE EXPOSED FROM TIME TO TIME REPRESENT THE MAJOR PUBLIC HEALTH THREAT OF THIS DECADE, AND IT IS OUR POSITION THAT ACTION IS NEEDED NOW TO INSURE THE EFFECTIVE IMPLEMENTATION OF (PL94-469).

I APPEAR TODAY ALSO AS A REPRESENTATIVE OF THE STATE OF NEW JERSEY WHERE CHEMICAL PRODUCTION, DISTRIBUTION, AND STORAGE FACILITIES ARE AS HIGHLY CONCENTRATED AS IN ANY STATE IN THE NATION. PARENTHETICALLY, SIXTY_FIVE OF THE TOP CHEMICAL DUMPS EXIST IN OUR STATE, AND WE ARE STRIVING TO CONTINUE THE DECELERATION OF CANCER DEATH RATES WHOSE MAGNITUDE PROBABLY BEARS A DIRECT RELATIONSHIP TO OUR INDUSTRIAL DEVELOPMENT ESPECIALLY IN CHEMICAL AND DRUG MANUFACTURE. NEW JERSEY NOW HAS THE HIGHEST MORTALITY RATES FOR BLADDER CANCER IN WHITE MALES WHICH UNDOUBTEDLY REPRESENTS THE EFFECT OF CHEMICAL EXPOSURES OF TWENTY TO THRITY YEARS AGO.

THESE HUMAN CHEMICAL EXPOSURES MAKE IT IMPERATIVE THAT THE TSCA LEGISLATION BE ADMINISTERED IN SUCH A MANNER AS TO HELP NEW JERSEY AND OTHER INDUSTRIAL STATES TO KNOW MORE CLEARLY WHERE THEY STAND IN TERMS OF TOXIC AND MORTALITY RISKS, AND TO PREVENT FURTHER UNDESIRABLE EFFECTS FROM NEW PRODUCTS.

THE TSCA PROPOSAL WAS INTENDED TO BE ENACTED IN 1970 WHEN A NEW CONCERN FOR THE PUBLIC HEALTH IMPLICATIONS OF TOXIC SUBSTANCES WAS GROWING RAPIDLY IN THE UNITED STATES.

THE CONGRESS BEGAN TO ENUNCIATE POLICIES TO CONTROL TOXIC SUBSTANCES IN THE WORKPLACE AND ENVIRONMENT NEARLY 25 YEARS AGO WHEN THE FEDERAL HAZARDOUS SUBSTANCES LABELING ACT WAS PASSED IN 1960, THE NATIONAL ENVIRONMENTAL POLICY ACT WAS APPROVED IN 1969, THE FEDERAL COAL MINE HEALTH AND SAFETY ACT WAS PASSED IN 1969, AND THE ENVIRONMENTAL PROTECTION AGENCY AND THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION WERE FORMED IN 1970.

IT REMAINED ONLY TO FORMULATE LEGISLATION ASSURING THE EXISTENCE OF A DATE BASE COVERING THE 55,000 SIGNIFICANT SUBSTANCES OF POTENTIAL TOXICITY IN COMMERCIAL USE, TO DESIGN A PREVENTIVE STRATEGY SO THAT THE 1,000 NEW CHEMICALS ADDED ANNUALLY WOULD BE TESTED BY INDUSTRY BEFORE GENERAL USE, AND TO PIN POINT, AVOID, OR REMOVE THE MOST DANGEROUS PRODUCTS. THE TSCA PASSED IN 1976 PROMISED TO ACCOMPLISH THESE GOALS. IF IT HAD SUCCEEDED PERHAPS THE PEOPLE OF TIMES BEACH AND NEWARK, NEW JERSEY WOULD HAVE BEEN AWARE OF THE PRESENCE OF DIOXIN AS A BY-PRODUCE OF THE MANUFACTURE OF THE HERBICIDES 2,4,5,T, and 2,4,D.

PUBLIC HEALTH AUTHORITIES WOULD HAVE BEEN ABLE TO RESPOND MORE PROMPTLY TO PROTECT THE POPULATION AGAINST MANIFEST AND POTENTIAL HUMAN EFFECTS OF THIS DEADLY SUBSTANCE.

THE LAW HAS SEVERAL STRONG FEATURES-COMPLETION OF AN INVENTORY, AN INTERAGENCY COMMITTEE TO IDENTIFY THE 50 MOST NOXIOUS AGENTS IN TERMS OF CANCER, BIRTH DEFECTS, CHROMOSOMAL CHANGES AND HOW THEY ARE TO BE TESTED, POWER TO BAN SALE OF HIGH RISK PRODUCTS, REQUIREMENT OF

LABELING, PUBLIC INFORMATION WITH RESPECT TO THOSE TOXIC PRODUCTS IN USE, FUNDS FOR STATE GRANTS TO SUPPLEMENT FEDERAL ACTIONS, ETC.

WHAT HAVE BEEN THE FAILURES OF EPA?

1. WHEREAS THE LAW REQUIRES PORDUCER OR PROCESSOR TESTING OF NEW SUBSTANCES IF DEEMED A POTENTIAL RISK, ABOUT HALF OF THE COMPOUNDS REPORTED TO EPA HAVE BEEN SUMMARILY EXONERATED, MOST OF THE REST HAVE BEEN THE SUBJECT OF VOLUNTIARY AGREEMENTS WITH THEIR ORIGINATORS, AND POSING RULES FOR EACH, WHICH WOULD HAVE REQUIRED PUBLIC COMMENT, AHS BEEN AVOIDED.

2. FURTHERMORE, THE INFORAMTION ON NEW PRODUCTS HAS BEEN SKETCHY AND LACKING IN THE MOST ESSENTIAL INGREDIENTS, I.E. TOXIC PROPERTIES.

THERE HAVE BEEN OTHER SERIOUS DEFICIENCIES IN ADMINISTRATION:

3. FAILURE TO INFORM THE PUBLIC ADEQUATELY:

4. FAILURE TO BAN ANY NEW SUBSTANCES AND HALTING AND INADEQUATE CONTROLS OVER PCB'S AND ASBESTOS WHICH WERE ALL READY OF MAJOR PUBLIC AND SCIENTIFIC CONCERN WHEN THE ACT WAS PASSED.

5. IN ADDITION TO INADEQUTE ADMINISTRATION, FINANCIAL SUPPORT OF EPA PARTICULARLY FOR STAFF NEEDED TO REVIEW NEW SUBSTANCES, AND ASSISTANCE TO STATES HAS SEVERELY CRIPPLED OPERATIONS.

ANOTHER BASIC DEFECT IS THE LACK OF RELIANCE ON PUBLIC HEALTH AND EPIDEMIOLOGIC EXPERTISE IN THE U.S. PUBLIC HEALTH SERVICE.

TESTING OF TOXIC SUBSTANCES OFTEN REQUI$RE HUMAN CASE CONTROL STUDIES, AND PRODUCERS OF CHEMICALS GENERALLY DO NOT POSSESS THAT KIND OF EXPERTISE.

IN SUMMARY, WE HAVE A GOOD BILL IN THE PUBILC INTEREST WHICH IS SUPPORTED IN ITS BASIC PROVISIONS BY THE PUBLIC HEALTH PROFESSION, BUT WHICH THROUGH INADEQUATE ADMINISTRATION AND FINANCIAL SUPPORT HAS MADE A MOCKERY OF ITS INTENT-TO PROTECT "HUMAN BEINGS AND THE ENVIRONMENT (WHICH ARE) BEING EXPOSED EACH YEAR TO A LARGER NUMBER OF CHEMICAL SUSTANCES."

IN VIEW OF OUR CONCERNS FOR ADMINISTRATION, APHA RECOMMENDS THE FOLLOWING:

1. THE ACT BE ENFORCED AS INTENDED UNDER THE ENVIRONMENTAL PROTECTION AGENCY WITH REINFORCEMENT OF THIS RESPONSIBILITY THROUGH RESOLUTION OF CONGRESS OR OTHER MEANS AVAILABLE:

2.. THAT CONGRESS REAFFIRM THAT HUMAN HEALTH NEEDS SHALL TAKE PRECEDENCE OVER COMMERCIAL OBJECTIVES:

3. THAT THE PBULIC HEALTH IMPLICATIONS OF THE LEGISLATION BE STRENGTHENED THROUGH ADMINISTRATIVE ACTIONS AS FOLLOWS:

A- THE ASSISTANT SECRETARY FOR HEALTH OF THE DHHS, AND PBULIC HEALTH SERVICE STAFF BE REQUIRED TO PLAY A MORE EFFECTIVE POLICY MAKING ROLE:

B- THE ADEQUACY OF EPIDEMIOLOGIC METHODS FOR SUBSTANCE TESTING BE EMPHASIZED.

4. THAT EVENTUALLY THE EPA BE MERGED WITH THE US PUBLIC HEALTH SERVICES TO RESTABLISH THE INCLUSION OF ALL ENVIRONMENTAL HEALTH PROGRAMS AS PART OF THE MAINSTREAM OF BASIC PUBLIC HEALTH OPERATIONS.

5. SHOULD IT PROVE THAT HUMAN PROTECTION AGAINST THE RISK OF TOXIC SUBSTANCES PLACES AN INORDINATE SOCIAL AND EOCNOMIC BURDEN ON A PRODUCER OR COMMUNITY, AS IN THE RECENT TACOMA, WASHINGTON SITUATION, MORE EFFECTIVE LEGISLATIVE REMEDIES MAY BE NECESSARY. WHEN A CHEMICAL PRODUCT IS VITALLY NEEDED UNDER SUCH CONDITIONS CONSIDERATION SHOULD BE GIVEN TO PUBLIC INTERVENTION THROUGH GRANTS, LOANS, OTHER FEDERAL AID, OR IF NECESARY IN THE PBULIC INTEREST, SUCH AN ENTERPRISE MAY NEED TO BE CONVERTED TO A PUBLICLY HELD CORPORATION. THIS WOULD BE THE LAST RESORT REMEDY TO INSURE THE AVAILABILITY OF NEEDED PRODUCTS, WHILE AT THE SAME TIME PROTECTING HUMANS AGAINST TOXIC EXPOSURE DESPITE THE ECONOMIC SITUATION AFFECTING A PARTICULAR PRODUCER OR COMMUNITY.

ORAL STATEMENT
BEFORE THE SENATE TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT SUBCOMMITTEE
AUGUST 1, 1983

GOOD MORNING, MY NAME IS RON CONDRAY. I AM EMPLOYED BY MONSANTO COMPANY IN ST. LOUIS, MISSOURI, AND HAVE CORPORATE RESPONSIBILITY FOR REGULATORY MANAGEMENT OF THE TOXIC SUBSTANCES CONTROL ACT.

MONSANTO PRODUCES A WIDE RANGE OF PRODUCTS INCLUDING COMMODITY CHEMICALS, SPECIALTY AND FINE CHEMICALS, POLYMERS AND PLASTICS, SYNTHETIC FIBERS, AGRICULTURAL AND NUTRITIONAL CHEMICALS AND ENGINEERED PRODUCTS. THE COMPANY EMPLOYS 38,000 PEOPLE IN THE UNITED STATES AND APPROXIMATELY HALF AGAIN THAT NUMBER IN THE REMAINDER OF THE WORLD. THE COMPANY'S U.S. OPERATIONS INCLUDE 60 PLANTS, AND 13 LABORATORY AND TECHNICAL CENTERS DOTTED ACROSS THE COUNTRY.

MONSANTO HAS HAD AN ACTIVE INTEREST IN THE TOXIC SUBSTANCES CONTROL ACT (TSCA) FROM THE TIME OF THE FIRST CONGRESSIONAL DISCUSSIONS IN THE EARLY 1970'S, UP TO THE PRESENT. THE COMPANY SUPPORTED PASSAGE OF THE ACT IN 1976 AND CONTINUES TO SUPPORT THE UNDERLYING PRINCIPLES, POLICY AND APPROACH OF THE LAW. WE HAVE SEEN SIGNIFICANT PROGRESS TOWARD ACHIEVING THE CONGRESSIONAL INTENT OF TSCA AND SEE NO REASON FOR LEGISLATIVE CHANGE.

THE ENVIRONMENTAL PROTECTION AGENCY (EPA) IS CHARGED WITH THE IMPLEMENTATION AND ENFORCEMENT OF TSCA AND HAVE BROAD AUTHORITY TO DO SO. WHILE

WE DON'T ALWAYS AGREE WITH EPA'S RULEMAKING ACTIVITIES, WE DO BELIEVE THAT THE TSCA FRAMEWORK COUPLED WITH THE RULEMAKING PROCESS OF PROPOSAL AND COMMENT HAS RESULTED IN REASONABLY BALANCED IMPLEMENTATION.

THE LAW PROVIDES EPA WITH AUTHORITY TO ACT QUICKLY ON THOSE SITUATIONS INVOLVING IMMINENT HAZARD. ON OTHER TOXIC SUBSTANCES ISSUES, EPA HAS THE OPPORTUNITY TO REVIEW AND WEIGH THE SCIENCE, POLICY AND ECONOMIC PARAMETERS, PRIOR TO DECISIONMAKING. WE BELIEVE THAT THIS APPROACH HAS WORKED WELL AND IS EXTREMELY IMPORTANT BECAUSE OF THE COMPLEXITIES INVOLVED IN TOXIC SUBSTANCES ISSUES. PROPOSAL AND PUBLIC COMMENT VIA THE RULEMAKING PROCESS, WHILE AT TIMES FRUSTRATINGLY SLOW IS USUALLY THE MOST DESIRABLE WAY TO COME TO APPROPRIATE DECISIONS ON TSCA ISSUES. WE ALSO ENDORSE THOSE SITUATIONS WHERE DECISIONS CAN BE ACCELERATED THROUGH SCIENTIFIC DISCUSSIONS AND NEGOTIATED AGREEMENTS.

MONSANTO EXPERIENCE WITH TSCA HAS TAKEN SEVERAL FORMS.

1. TSCA HAS SERVED AS AN AUDIT FUNCTION FOR OUR INTERNAL PRODUCT SAFETY PROGRAMS.
2. TSCA IN CONCERT WITH OTHER HEALTH AND ENVIRONMENTAL LAWS HAS BROUGHT AN INCREASED AWARENESS OF TOXIC SUBSTANCES ISSUES TO MONSANTO MANAGEMENT.
3. THE LAW HAS PROVIDED INCREASED SENSITIVITY AND A DEGREE OF UNIFORMITY ACROSS THE CHEMICAL INDUSTRY ON

HEALTH AND ENVIRONMENTAL ISSUES AND HAS SERVED AS A SAFETY NET TO PREVENT UNREASONABLE RISK.

4. TSCA HAS INCREASED THE COST OF DOING BUSINESS. THESE COSTS TAKE SEVERAL FORMS SOME OF WHICH WE FEEL ARE JUSTIFIED, OTHERS WE SERIOUSLY QUESTION.

LET ME EXPAND ON THESE POINTS --

MONSANTO HAS AN ACTIVE PROGRAM OF ASSESSING NEW AND EXISTING CHEMICALS. WE UTILIZE BOTH INTERNAL AND EXTERNAL SCIENTISTS IN THIS REVIEW. THIS ACTIVITY HAS BEEN IN PLACE FOR A NUMBER OF YEARS AND IS PART OF OUR PRODUCT SAFETY PROGRAM. WE ASSESS NEW CHEMICALS AND TEST THEM AS NECESSARY BEFORE COMMERCIALIZATION. WE MONITOR, TEST AND ASSESS OUR EXISTING FAMILY OF CHEMICALS ON A CONTINUING BASIS AND TAKE ACTION AS APPROPRIATE. PRODUCT SAFETY IS PART OF OUR SOCIAL RESPONSIBILITY COMMITMENT AND IT'S JUST GOOD BUSINESS FROM BOTH A CUSTOMER RELATIONS VIEW AND A LEGAL LIABILITY PERSPECTIVE.

EPA'S PROGRAMS UNDER TSCA HAVE PROVIDED AN EXTERNAL REVIEW OR AUDIT OF OUR PRODUCT SAFETY ACTIVITIES. FOR EXAMPLE, BEFORE A NEW CHEMICAL CAN BE MANUFACTURED, WE MUST SUBMIT A PREMANUFACTURING NOTICE (PMN) TO EPA. THIS NOTICE AND REVIEW BY EPA PROVIDES A CROSSCHECK ON OUR INTERNAL REVIEW PROCESS. TO DATE, WE HAVE SUBMITTED IN EXCESS OF 25 PMN'S. WE PROVIDE IN THE NOTICE, INFORMATION AS REQUIRED BY THE ACT, PLUS DATA AND INFORMATION DEVELOPED DURING OUR INTERNAL REVIEW. THE OPTIONAL

INFORMATION VARIES CONSIDERABLY DEPENDING ON THE MATERIAL TYPE, AND THE USE PLANNED FOR THE SUBSTANCE.

TESTING INFORMATION PROVIDED WITH THE PMN ALSO VARIES. FOR SOME MATERIALS, TESTING IS NECESSARY TO CLARIFY POTENTIAL CONCERNS. FOR THESE MATERIALS, THE TEST PROGRAMS ARE TAILORED TO THE SPECIFIC CHEMICAL AND ITS ANTICIPATED EXPOSURE. IF, FOR EXAMPLE, THE SUBSTANCE WILL FIND ITS WAY INTO THE AQUATIC ENVIRONMENT IN SIGNIFICANT AMOUNTS, WE FEEL IT IS IMPORTANT TO KNOW IF IT BIODEGRADES AND HOW FAST. FOR OTHER MATERIALS SUCH IS NOT THE CASE, AND LITTLE IF ANY TESTING IS NEEDED. FOR THESE MATERIALS, SUCH AS STRUCTURAL POLYMERS SIMILAR TO OUR EXISTING PRODUCT LINES, OUR SCIENTIFIC REVIEW PANEL ARE OF THE OPINION THEY CAN RELIABLY ASSESS THE HAZARDS BASED ON THEIR KNOWLEDGE AND EXPERIENCE.

FOR ALMOST ALL OF OUR PMN SUBMISSIONS, WE HAVE BEEN CONTACTED BY EPA ASKING CLARIFYING QUESTIONS. IN A COUPLE OF CASES, WE HAVE BEEN CHALLENGED AND HAVE BEEN REQUIRED TO PROVIDE ADDITIONAL INFORMATION TO SUPPORT OUR POSITIONS. IN OUR EXPERIENCE, EPA IS PROVIDING A THOROUGH AND PROFESSIONAL REVIEW OF PMN'S.

EPA RECENTLY ISSUED FINAL PMN RULES. WHILE WE DON'T BELIEVE SUCH RULES ARE NECESSARY IN VIEW OF THE SUCCESSFUL PROCESSING OF OVER 2,500 PMN'S TO DATE BY THE AGENCY, WE ARE VERY CONCERNED WITH LANGUAGE IN THE RULE REGARDING REGULATORY MANAGEMENT OF NEW SUBSTANCES AT THE (RESEARCH AND DEVELOPMENT) R&D STAGE. IF INTERPRETED

LITERALLY, THE RULE WOULD REQUIRE A COMPLETE CHANGE IN THE WAY R&D IS CURRENTLY HANDLED WITH LITTLE, IF ANY, BENEFIT TO HEALTH OR ENVIRONMENT. THE NET EFFECT WILL BE A DAMPER ON NEW PRODUCT INNOVATION. EPA IS RECONSIDERING THIS FACET OF THE RULE AND WE ARE HOPEFUL THAT OUR CONCERNS WILL BE TAKEN INTO ACCOUNT DURING THIS REVIEW.

EPA HAS OTHER PROGRAMS UNDER TSCA THAT ALSO PROVIDE AN AUDIT ON OUR PRODUCT SAFETY PROGRAM. IN 1982, WE SPENT IN EXCESS OF TEN MILLION DOLLARS TESTING THE HEALTH AND ENVIRONMENTAL EFFECTS OF OUR PRODUCTS AND RAW MATERIALS. WE ARE ALSO A FINANCIAL SUPPORTER OF THE CHEMICAL INDUSTRY INSTITUTE OF TOXICOLOGY AND ACTIVELY MONITOR FEDERAL TESTING PROGRAMS AND THE SCIENTIFIC LITERATURE. THESE PROGRAMS ARE DESIGNED TO PROVIDE THE SCIENTIFIC BASE NECESSARY TO ENSURE THAT OUR PRODUCTS AND WORKPLACE MATERIALS DO NOT POSE AN UNREASONABLE RISK.

THE INTERAGENCY TESTING COMMITTEE (ITC) AND EPA PROVIDE AN EXTERNAL AUDIT OF OUR TESTING PROGRAM. BOTH THE ITC AND EPA PRIORITIZE CHEMICALS THAT HAVE DATA GAPS AND IDENTIFY SPECIFIC TESTING NEEDS. THIS PROCESS GOT OFF TO A ROCKY START, BUT HAS IMPROVED SIGNIFICANTLY. ITC SCREENING PROCEDURES ARE NOW RECOGNIZED AS STATE-OF-THE ART AND CURRENT INFORMATION GATHERING PROCEDURES HAVE GREATLY IMPROVED ITC'S DATA BASE.

MONSANTO HAS PROVIDED INPUT TO BOTH GROUPS TO ASSIST IN THEIR DECISIONMAKING. FOR EXAMPLE, APPROXIMATELY 30

REPORTS DEALING WITH EXPOSURE OF MONSANTO PRODUCTS WAS RECENTLY PROVIDED TO EPA FOR ASSESSMENT PURPOSES. WE HAVE SUBMITTED COPIES OF OVER 550 HEALTH AND SAFETY STUDIES TO EPA FOR REVIEW. (THIS GROUP OF STUDIES TRANSLATES TO A STACK OF PAPER TEN FEET HIGH.) OVER THE LAST TWO YEARS, WE HAVE VOLUNTARILY SUBMITTED INFORMATION ON OVER 30 MATERIALS UNDER EVALUATION BY ITC. WE ARE INVOLVED IN NEGOTIATED TESTING AGREEMENTS ON A HALF A DOZEN CHEMICALS AND CHEMICAL FAMILIES, SEVERAL OF WHICH HAVE REACHED CLOSURE AND NEW TEST DATA IS IN EPA'S HANDS. TEST RULES INVOLVING MONSANTO PRODUCTS ARE ALSO UNDER DEVELOPMENT BY THE AGENCY, AND WE ANTICIPATE THESE TESTING COSTS TO BE SIGNIFICANT. EACH OF THE ABOVE-MENTIONED STATISTICS REPRESENTS AN EXTERNAL INPUT OR AUDIT ON MONSANTO'S TESTING AND ASSESSMENT PROGRAM AND PRIORITIES.

TURNING NOW TO POINT 2, TSCA MUST BE LOOKED AT IN CONCERT WITH AN ARRAY OF OTHER HEALTH AND ENVIRONMENTAL LAWS SUCH AS THE CLEAN AIR AND WATER ACTS, THE RESOURCE CONSERVATION AND RECOVERY ACT, AND THE OCCUPATIONAL HEALTH AND SAFETY ACT, TO MENTION A FEW. TSCA IS PERVASIVE IN THAT IT COVERS THE CHEMICAL INDUSTRY BROADLY BUT, AT THE SAME TIME, IT IS DESIGNED AS A "GAP-FILLER" TO MINIMIZE OVERLAP WITH OTHER LAWS. TAKEN AS A GROUP, THESE LAWS HAVE BROUGHT TO MONSANTO MANAGEMENT VISIBLE EVIDENCE OF PUBLIC SUPPORT FOR THE

SIGNIFICANT CORPORATE EXPENDITURES AND RESOURCE COMMITMENT TO MONSANTO'S PRODUCT SAFETY PROGRAMS.

MONSANTO IS NOT ALONE IN ITS GENERALLY INDEPENDENT APPROACH TO TSCA. HOWEVER, TSCA HAS SERVED TO BRING THE CHEMICAL INDUSTRY TOGETHER TO DISCUSS THE TOXIC SUBSTANCES ISSUES. MONSANTO HAS BEEN ACTIVELY INVOLVED WITH SEVERAL TRADE ASSOCIATIONS ON TSCA ISSUES AND I CURRENTLY CHAIR THE CHEMICAL REGULATIONS ADVISORY COMMITTEE OF THE CHEMICAL MANUFACTURERS ASSOCIATION. INDUSTRY DISCUSSIONS AMONGST OURSELVES AND WITH THOSE EXTERNAL TO THE ASSOCIATIONS HAVE BEEN HEALTHY. THIS ACTIVITY HAS BROUGHT ABOUT AN INCREASED AWARENESS ON THE PART OF THOSE INVOLVED AND AN UPGRADING OF PRODUCT SAFETY IN GENERAL. ON THE OTHER HAND, TSCA, AND EPA SPECIFICALLY, SERVE AS A SAFETY NET FOR THOSE LESS INFORMED OR JUST RECALCITRANT REGARDING APPROPRIATE PRODUCT SAFETY PROGRAMS. EXAMPLES OF THE SAFETY NET IN ACTION CAN BE SEEN IN THE PMN PROGRAM, THE 8(e) SUBSTANTIAL RISK NOTIFICATION PROGRAM AND EPA'S EXISTING CHEMICAL PROGRAM THAT IS JUST NOW DEVELOPING INTO FULL BLOOM.

PROGRESS UNDER TSCA HAS NOT COME WITHOUT SIGNIFICANT COST. TRUE, MONSANTO'S PRODUCT SAFETY PROGRAM ACCOUNTS FOR A MAJOR PART OF THE EXPENDITURES AND RESOURCES FOR MANAGEMENT OF TOXIC SUBSTANCES. WE HAVE, HOWEVER, SEEN NUMEROUS EXAMPLES WHERE; AN EPA PRIORITY OR DIRECTION WAS DIFFERENT THAN ONE WE WOULD HAVE CHOSEN; BURDENS IMPOSED

BY RULES GO FAR IN EXCESS OF THE BENEFITS THEY PRODUCE; REGULATORY DECISIONS LACK THE NECESSARY SCIENTIFIC SUPPORT; AND WHERE PRACTICAL APPROACHES ARE NOT GIVEN ADEQUATE CONSIDERATION. THESE PROBLEMS ARE, HOWEVER, AMENABLE TO EPA ADMINISTRATIVE SOLUTIONS AND THE LAW IS NOT AT FAULT. EPA HAS MADE SIGNIFICANT EFFORTS TO UNDERSTAND THESE AND SIMILAR PROBLEMS. THE REGULATORY PROCESS OF PROPOSAL AND COMMENT HAS BEEN THE PRIMARY VEHICLE AND WE HAVE SEEN EXAMPLES WHERE OUR CONCERNS HAVE BEEN REFLECTED IN EPA ACTIONS AND FINAL RULES.

IN SUMMARY, I URGE THE COMMITTEE ON BEHALF OF MONSANTO TO REAUTHORIZE TSCA IN ITS PRESENT FORM. THE FLEXIBILITY PROVIDED BY THE LAW COMPLEMENTS INDUSTRY PRODUCT SAFETY PROGRAMS SUCH AS THOSE IN PLACE AT MONSANTO. AT THE SAME TIME, TSCA PROVIDES THE NECESSARY SAFETY NET TO ENSURE THAT CHEMICALS DO NOT POSE AN UNREASONABLE RISK TO HEALTH AND ENVIRONMENT. WE BELIEVE THAT EPA HAS ACCEPTED THE RESPONSIBILITY AND MADE GREAT STRIDES TOWARD IMPLEMENTING AND ENFORCING THE ACT TO ENSURE COMPLIANCE WITH CONGRESSIONAL INTENT. PROBLEMS WE HAVE HAD TO DATE WITH TSCA ARE BEST HANDLED, WE BELIEVE, THROUGH THE NORMAL REGULATORY PROCESS.

THANK YOU FOR THE OPPORTUNITY TO PRESENT OUR VIEWS TO THE COMMITTEE.

Monsanto

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

November 9, 1983

The Honorable David Durenberger
Chairman, Subcommittee on Toxic Substances
and Environmental Oversight
United States Senate
Senate Russell Building
Third Floor
Washington, D.C. 20510

Dear Senator:

Attached you will find responses to the nine questions posed in your October 5, 1983 letter. These questions and responses are followup to the testimony on toxic substances I presented before your subcommittee on August 1, 1983.

I appreciate the opportunity to present my views and those of Monsanto on the subject of toxic chemicals and more specifically, the way in which the Toxic Substances Control Act is dealing with the situation. The highly technical nature of some of the questions, especially number nine, suggest the need for more indepth discussion over and above the enclosed responses.

On behalf of Monsanto, I would like to extend a welcome to you, other members of your subcommittee and members of the subcommittee staff to visit our General Offices and Laboratories here in St. Louis. We would like very much to discuss in more depth the programs Monsanto uses to evaluate the safety and environmental compatibility of Monsanto products and workplace materials. I hope that such a visit can be scheduled in the future.

Sincerely,

Ron Condray

J. R. Condray
Director, Regulatory Management
Toxic Substances
Environmental Policy Staff

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Att.

DRAFT

Responses to Questions Posed to J. Ronald Condray, Monsanto Company by The Chairman of The Senate Subcommittee on Toxic Substances and Environmental Oversight - October 5, 1983

Q1. When Congress enacted TSCA it was concerned that required testing might overwhelm available testing capacity.

- Did your company expand its laboratory testing capacity and budget for testing at the time TSCA was enacted?

- If so, has that capacity been fully utilized?

- Do you have any information or impressions about the extent to which the testing capacity of independent laboratories is being utilized at the present time?

A1. In the mid-seventies, Monsanto commissioned the Environmental Health Laboratory (EHL) as an in-house facility to support our ongoing product stewardship programs.

The in-house facility was brought on stream to provide Monsanto with greater flexibility to ensure that needed tests were performed in a timely and well-managed fashion. Monsanto was faced at the time with increased testing demands brought on by product growth in the areas of pesticides, herbicides, food additives, and drugs that require extensive testing. Anticipated regulatory requirements under FIFRA, FFDCA and TSCA were also a factor.

These facilities were not designed to handle Monsanto's entire testing needs and as such, they have been and are currently fully utilized. Monsanto supplements EHL with outside testing laboratories. In recent times, our toxicology department has not had major difficulty placing needed test work with outside laboratories. This suggests that there may be some current over capacity in independent laboratories. We believe that some over capacity is desirable to allow competitive market forces to come into play and ensure that quality work meeting state-of-the-art Good Laboratory Practices (GLP) is accomplished in a timely manner.

Q2. OTA testified that toxicity data were reported more often for site-limited intermediate chemicals than for other new chemicals. It was suggested that this is due to a concern for worker safety and a desire on the part of employees to be informed about possible hazards to their employees.

Do you think a concern for workers is behind the testing of site-limited intermediates?

If potential risk to workers is of such concern that companies emphasize testing for site-limited intermediates, then is it wise for EPA to exempt these chemicals from PMN requirements as the Agency has proposed to do so?

A2. It is true that OTA found that more test data were submitted for site-limited new chemicals than for other PMN substances. In comparing "other" PMN substances to site-limited chemicals, however, OTA considered both polymers and non-polymers. As OTA concluded elsewhere in its report, (1) fewer toxicity data are submitted for polymers than for other PMN substances because "polymers high molecular weight makes them inactive in most biological systems." For this reason, polymers should be excluded from any comparison of the amounts of toxicity testing performed on site-limited chemicals and other PMN substances. After making such an exclusion, OTA's data show that site-limited chemicals were in fact tested somewhat less extensively than other PMN substances. (2)

We do not agree that, because of their potential for workplace exposure, site-limited chemicals are of more concern than other classes of PMN substances and warrant more extensive testing. Site-limited intermediates are consumed at the plants where they are manufactured and, hence, are generally used under highly controlled conditions which limit exposure or release. Moreover, the employee populations that handle these chemicals are typically small in size and carefully trained in the use of protective equipment and other precautions. For these reasons, site-limited chemicals are unlikely to pose significant risks to workers or the general population. There may be some site-limtied intermediates that, because of their reactivity, warrant careful toxicological evaluation. However, it would be mistaken to assume that, as a general rule, site-limited intermediates need more testing than other PMN substances.

EPA's inclusion of site-limited intermediates in its exemption proposal under Section 5(h)(4) is based on a recognition that the exposure potential of these chemicals is limited. It should be noted, however, that site-limited intermediates would not automatically be exempted from PMN requirements under EPA's proposal. Rather, no site-limited intermediate would be eligible for exemption if it (a) could cause serious acute or chronic health effects, or significant environmental effects, under its anticipated conditions of use or (b) is known or suspected to have carcinogenic or teratogenic potential or has produced positive results in mutagenicity tests. To apply these criteria, each exemption candidate would first be evaluated by a "qualified expert" selected by the manufacturer, and then by EPA, before the start of production. These safeguards are more than adequate to protect the health of workers exposed to site-limited intermediates that qualify for exemption. Indeed, the chemical industry has emphasized that EPA's exemption proposed is unnecessarily stringent.

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(1) Office of Technology Assessment, The Information Content of Premanufacture Notices (1982), at 58.

(2) OTA Report at 62-64.

Q3. Please provide the following information about your company's experience with TSCA requirements?

(a) How many PMN's have you filed?

(i) Of these, how many have been subjected to "detailed review" by EPA?

(ii) How many have you subsequently withdrawn because of concern about the chemical?

(iii) How many have been the subject of an EPA request for additional information beyond that you originally submitted?

(iv) In how many cases have you performed additional tests at EPA's request after the date of original submittal?

(b) How many section 8(d) notices have you filed?

(c) How many section 8(e) notices have you filed?

A3. (a) Monsanto has submitted a total of 31 PMN's.

(i) To the best of our knowledge, all of our PMN's have been fully reviewed by EPA.

(ii) None of the Monsanto PMN's have been withdrawn because of EPA concern about the chemical. One of our first PMN's was returned to Monsanto because it was for export only.

(iii) Most of Monsanto's PMN's have resulted in additional information transfer to EPA. Most of the information has been in the form of clarification and has been handled via phone communications. Technical references, detailed process or use information or test protocols have been provided to EPA as part of this followup activity.

(iv) One PMN substance has been subject to additional toxicological testing at the request of EPA.

(b) Monsanto has submitted a total of 588 health and safety studies as a result of 8(d) notices published by EPA.

(c) One section 8(e) notice has been filed with the EPA by Monsanto. In several other instances, Monsanto has provided information to EPA, though not required to do so by Section 8(e).

Q4. Dr. Davies testified that the chemical industry argued in the mid-70's that TSCA was unnecessary because firms already performed adequate testing, including testing of new chemicals. However, in general, little data is being submitted to EPA in PMN's.

- Does your company now do more or less testing of new chemicals as a result of TSCA? Has TSCA changed the incentive to conduct testing? Are you more or less likely to test independently, or are you likely to wait until EPA tells you to test?

A4. As I testified before your committee on August 1, 1983, Monsanto has had a product stewardship program for many years. This program includes testing to ensure that our products are safe for their intended uses. From discussion with my colleagues in the Chemical Manufacturers Association, I don't think our our current program is unique in this regard. As a result, I believe that Dr. Davies' comment that "in general, little data is being submitted to EPA in PMN's" doesn't accurately describe the situation. I contend that where data is needed to conduct a meaningful evaluation of a new chemical for its intended manufacture or use, that such data is available.

Because of Monsanto's inplace product stewardship program, which includes assessment and, where appropriate, testing of new chemicals, TSCA has had a limited effect on the company's new product test program. In a few situations, we have performed additional tests, over-and-above what we think is necessary, to insure smooth passage of a PMN through the EPA review process. As stated in question 3, in one case we did additional testing at EPA's request. Both of these cases are exceptions rather than the rule.

Q5. Dr. Gough of the Office of Technical Assessment said that he was surprised how few PMN's included chronic health effects information; asked why he thought so little testing was done, he said he didn't know, but that he doubted cost was a factor because a mutagenicity test, at least, is inexpensive.

- Are you surprised that so few new chemicals have been tested for mutagenicity? And why do you think industry has not been conducting such tests?

A5. There are a number of factors that need to be considered to justify chronic effects testing. Some of these factors include exposure potential, potential biological activity, reliability of the tests involved, and probability of commercial success. Many materials cannot justify chronic testing at the PMN stage of commercialization due to the low level of exposure.

There is a great deal of uncertainty regarding the predictive value of mutagenicity test results, particularly the short-term (in vitro) assays, for human risk assessment. Such short-term studies are presently generally used as an early screening tool rather than providing a realistic prediction of possible chronic health effects related to a new chemical. Each new material must be evaluated on a case-by-case basis as to whether short term assays could provide useful screening information.

The utility and inexpensiveness of conducting a single short-term (in vitro) mutagenicity study are highly misunderstood concepts. There is no single mutagenicity study that can be used successfully to screen for all possible genotoxic effects. Thus, the use of a "battery approach" (3-4 short term tests at a minimum) is considered by many to be a more appropriate approach.

Costs associated with conducting individual short-term studies are increasing as our understanding in the science progresses. We are learning that even these "simple" assays require redesign to insure proper verification of results. This redesign is adding substantially to the once nominal costs of many of these studies. In addition, the cost of conducting a battery of studies for a single new chemical obviously will substantially exceed that which could have been spent if a single short-term study were conducted.

Q6. There have been reports over the years about the possible adverse impact TSCA may have in terms of innovation of new chemicals. Has your company seen a large reduction in new chemical development as a result of TSCA?

- Are there many products your company would produce if TSCA didn't exist?

- Can you give some descriptive examples of "safe" and probably profitable chemicals that you did not attempt to manufacture as a direct result of the cost of filing a PMN?

A6. While the costs and internal scrutiny required to develop a PMN are significant, they are not a major deterrent to Monsanto's major new product programs. Such programs typically focuses on large scale new ventures with significant revenue generating capability. Some of our new product developments with highly uncertain commercial possibilities, such as new products for existing markets with marginal cost/benefit advantages, have had difficulty justifying PMN costs.

I am not aware of any "safe" and probably profitable new chemical for which the cost of submitting a PMN was a deterrent to Monsanto. However, other companies with different product profiles might give a quite different answer to this question.

Q7. EPA's testimony stated that TSCA regulatory authority under section 6 applies "only if actions under other laws or by other Federal agencies are not forthcoming."

It also stated in section 9 of TSCA "Congress directed EPA... to defer action to other laws when authority to take action exists elsewhere."

Do you agree with EPA's interpretation of the requirements of section 9?

A7. As EPA's remarks suggest, TSCA was intended to be a "gap-filling" statute, to be invoked only where other laws are insufficient to protect health and the environment from unreasonable risks. Section 9 of TSCA speaks to this point. Section 9(a) requires EPA to submit a report to another federal agency when it identifies an unreasonable risk which the other agency has sufficient authority to control. EPA must then allow the other agency at least 90 days to decide whether to initiate action under the laws it administers. Section 9(b) provides that, where a risk to health or the environment can be addressed under another statute administered by EPA, the Agency must proceed under that statute unless it concludes that it is in the "public interest" to regulate under TSCA.

The requirements of Section 9 serve two important purposes. First, they serve the practical purpose of minimizing duplication of effort among the many federal agencies with responsibility for protecting human health and environment. Second, they assure that health and environmental concerns are initially addressed by those regulatory bodies which possess the greatest expertise. This will minimize conflicting regulatory requirements and eliminate unnecessary compliance burdens.

Section 9 grants EPA ample authority to invoke TSCA where health or environmental concerns cannot be effectively addressed under other laws. Under Section 9(a), EPA may initiate rulemaking under TSCA if, after receiving a report from EPA, another agency declines to take action to control a chemical. Moreover, adherence to the report procedure of Section 9(a) is necessary only if EPA concludes, in its discretion, that a particular risk can be "prevented or reduced to a sufficient extent" by action under a law other than TSCA. If EPA believes that other laws are not adequate to address the risk in question, it may immediately initiate rulemaking under TSCA.

To date, the requirements of Section 9 have not prevented EPA from proceeding with action under TSCA to control chemicals that could be regulated under other laws. For example, in 1980, EPA promulgated a rule under Section 6(a) of TSCA placing restrictions on the disposal of certain wastes concerning dioxin. 45 Fed. Reg. 32676 (May 19, 1980). EPA relied on TSCA rather than RCRA because its RCRA program was not yet fully implemented. As EPA concluded, it was in the "public interest" to use TSCA to provide interim protection against dioxin-containing wastes until more comprehensive approaches could be developed under RCRA.

More recently, EPA published advanced notice of proposed rulemaking on two chemicals, methelenedianiline and methylene bis (2-chloroaniline), that primarily raise workplace concerns. (48 Fed. Reg. 22954); (48 Fed. Reg. 42898). EPA is also considering proposing restrictions on the manufacture and use of asbestos even though its principal risks -- to exposed workers and consumers -- could be controlled by OSHA and the CPSC (44 Fed. Reg. 60061).

These examples demonstrate that, if anything, EPA has been more than willing to initiate action under TSCA where regulation under other laws would suffice to protect the public.

Q8. Many PMN's are submitted with most of the information claimed as confidential business information. Information in section 8(e) notices is often claimed confidential as well. EPA has testified that the Agency does not review a claim of confidentiality except in response to a request for the information filed under the Freedom of Information Act.

- Do you feel that present practices and procedures allow for adequate public oversight of EPA decisions?
- What kinds of information do you feel should be routinely held confidential to protect the manufacturer, and what information should be released to the public?
- Under what circumstances would it be appropriate for a company to claim as confidential the name of a chemical that has been implicated in causing a serious toxic effect?

A8. EPA's confidentiality procedures under TSCA strike an appropriate balance between the protection of legitimate trade secret information and the need for public oversight of EPA's regulatory functions. Any effort to weaken TSCA's confidentiality provisions would jeopardize important commercial needs without improving the quality of EPA's regulatory decisions.

The data included in PMN's frequently have great competitive value. The PMN will often provide a "blueprint" of the properties, process, and intended applications of an innovative new chemical that has not yet reached the marketplace. Thus, it is neither surprising nor disturbing that many companies request confidential treatment for a large amount of PMN information.

At present, EPA encourages public participation in the PMN process to the maximum extent consistent with the protection of confidential data. As required by Section 5(d) of TSCA, EPA publishes a Federal Register announcing the receipt of each PMN and establishes a public file relating to each PMN chemical. Persons dissatisifed with the amount of publicly available information on particular chemicals can file requests under the Freedom of Information Act (FOIA) for confidential data. If the manufacturer thereafter fails to substantiate his confidentiality claims, the data will be released. Where EPA upholds the data's confidentiality, the requester can invoke the legal remedies provided by the FOIA to challenge EPA's decision.

Significantly, EPA has received very few FOIA requests for PMN data, and no FOIA requester has filed suit against the Agency to challenge the withholding of confidential information. Equally important, I am not aware of any situation where lack of public access to confidential data hampered the Agency's review process under Section 5.

EPA's current approach of requiring substantiation of confidentiality claims upon the receipt of an FOIA request is consistent with the procedures of virtually every federal agency. It also represents a continuation of EPA's own longstanding practice under the laws it administers. To substantiate confidentiality claims at the time of PMN submittal would not only add significantly to the costs of the PMN process, but would be unnecessary in view of the small number of FOIA requests EPA receives for PMN information.

It is impossible to specify categories of information that should be held confidential on a routine basis. The need for confidential treatment will vary from manufacturer to manufacturer and chemical to chemical. EPA's final PMN rule (48 Fed. Reg. 41132) and instructions for use of the PMN Form (7710-25) provide for the type of confidentiality protection we think is appropriate. Types of information for which confidentiality claims can be made under the Rule include: production sites, company identity, and chemical identity. This list is not all-inclusive, however, and there will be occasions where more or less information will merit confidential treatment.

The only category of information for which confidential treatment is normally unavailable is "health and safety data," which EPA must disclose under Section 14(b) of TSCA except under certain narrow circumstances.

The fact that a chemical has been implicated in causing a serious toxic effect should not, in itself, bar a company from seeking confidential treatment for the chemical's identity. By describing the chemical identity and use in generic terms, and by disseminating appropriate labeling, Material Safety Data Sheets and other instructions, industry and concerned regulatory agencies may be able to develop and implement effective safeguards for handling or use. Of course, there may be some occasions where EPA decides that knowledge of the chemical's identity is essential to protect the public. In this event, Section 14(a)3 of TSCA would permit disclosure of this information if EPA determines that it is necessary "to protect health or the environment against an unreasonable risk of injury."

Q9. I assume you are familiar with the array of toxicity tests known as "Minimum Premarket Data", or MPD, that was developed by the OECD (copy attached). Let us assume that you had, for a particular chemical, good data from each type test listed in the MPD. Please rate as "good", "fair", "poor", or "not possible", the predictive ability of this set of data in terms of the potential for human toxicity of each of the following types: neurotoxicity, behavioral abnormalities, cancer, birth defects, gene defects, reproductive dysfunction, sublethal metabolic dysfunction, acute effects of various types.

Please explain whether and how your company assesses explicity the toxicity of a new chemical for each of these effects before it is marketed. Is there an official in your company who is required to sign off on the safety of a new chemical before it can be marketed?

A9. The first part of this question is difficult to respond to in a precise manner and would make for lively discussion at a toxicology forum or similar technical gathering. Some general comments from the Monsanto Toxicology Department are offered as follows:

Several of the adverse health effects listed can occur in an occupational or environmental setting under both acute (single exposure) and chronic conditions of contact. Such acute effects would generally be expected to occur only under excessively high exposures. Such instances are infrequent. The more prevalent exposure potential is one of a chronic nature, requiring repeated, longer-term exposure to far lower concentrations of a chemical.

The array of toxicity studies found in the "Minimum Premarket Data" (MPD) developed by the OECD, emphasize determination of acute toxicological effects. In most instances, their utility to predict similar effects under chronic exposure conditions are "poor" or "not possible." For instance, results from acute toxicity screening studies can provide a reasonable basis for predicting acute toxicological hazards (lethality, irritation, etc.) but provide little or no value in estimating the result of repeated exposure over a prolonged period of time. Similarly, results of mutagenicity studies yield "poor" or "no information" on most areas of toxicity mentioned. While results of repeated dose or bioaccumulation studies can yield useful information, these results cannot be directly related to the determination, and assessment, of some of the adverse health effects specified. Physical/chemical information cannot be used to determine adverse health effects but may be used to assess the hazard potential of a given chemical through determination that a given exposure condition appears unlikely (e.g, a material with a high vapor pressure to be used at ambient levels would be expected to present a low hazard from inhalation exposure).

As stated in answer 5, exposure is the key factor in justifying toxicological effects testing. Exposure of a repeated nature over prolonged periods of time are a major factor of consideration for chronic effects testing.

Monsanto assesses the safety and environmental compatibility of all new chemicals the company develops before they are marketed for commercial purposes. A number of factors are reviewed in the process including for example: toxicity, environmental fate, exposure and the physical and chemical properties of the material. Depending on the product and the nature of its use, a wide variety of tests might be required for comprehensive assessments. Trained toxicologists, industrial hygienists, and environmental effects experts combine their knowledge and skill to arrive at judgments regarding the exact tests to be performed.

The Office of the Monsanto Corporate Medical Department is the final judge on the adequacy of data developed to insure the safety and environmental capability of products sold.

STATEMENT OF JAY FELDMAN
NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES
BEFORE THE
SUBCOMMITTEE ON TOXIC SUBSTANCES
AND ENVIRONMENTAL OVERSIGHT
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
U.S. SENATE
AUGUST 1, 1983

Thank you for the opportunity to speak with you today. I am Jay Feldman, National Coordinator of the National Coalition Against the Misuse of Pesticides (NCAMP). I am pleased to be here to address pesticide use problems and the tremendous potential for harm, given their widespread use patterns and the poor state of our country's pesticide control program.

Our coalition's concern about toxic pesticides grows out of the experiences of our broad-based network of organizations and individuals in 50 states across the country. NCAMP is composed of members with common concerns about pesticide hazards and safety, including family farmers, farmworkers, beekeepers, chemical workers, consumers, and urban and rural residents alike.

The coalition seeks protection for all who may be exposed to pesticides, either through their employment, as consumers, as victims of contaminated drinking water, or as neighbors of dump sites, sprayed fields, forests or right-of-ways. NCAMP also promotes alternatives to excessive pesticide use and misuse, such as Integrated Pest Management (IPM), in an effort to reduce damage to humans and the environment, ease economic burdens over the long-run and improve general public and occupational health.

INTRODUCTION

While pesticides have been credited with enhancing our country's general quality of life, the dramatically rising use of these toxic chemicals also tampers irreversibly with our delicate ecological balance, often threatening our society's human and environmental health. Because of this a carefully constructed 'cradle to grave' control program is needed to assure adequate public protection from these poisons, which are deliberately added to our food, environment and consumer products. The existing statutory and regulatory program governing pesticide use takes a hit-or-miss approach to control and does not assure the public that marketed products are indeed safe.

A review of the U.S. Environmental Protection Agency's (EPA) pesticide program and its authorizing legislation, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), reveals numerous problems, such as:

1. the recently publicized faulty product safety testing data producted by the Industrial Bio-Test Laboratories, Inc. (IBT) and other labs;
2. no or inadequate health and environmental effects test data, including studies for cancer, birth defects and genetic damage, for the majority of products marketed today;

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3. virtually no public information on product risk;
4. backdoor product registration allowing the continual and expanded marketing of untested or poorly tested pesticides;

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6. nonenforcement of the federal law against violators, and;
7. the unconscionable exporting of banned or unregistered products.

The above represents some of the problems not only for the user of chemical pesticides --farmers, home gardeners and consumers of household products-- but literally for the entire society which is not directly handling toxic pesticides --consumers of food and water and those exposed through community spray programs or spray drift from farms, forests or right-of-ways.

The existing federal pesticide control program under FIFRA seeks to meet competing public and chemical industry goals. While the chemical industry wants to see the law assure speedy marketing of their pesticide products and protections for investments in product development, the public and worker population of this country want to see this law protect them, their families and the environment from exposure to toxic pesticides which have both short- and long-term health risk potential. In return for a registration number and exclusive-use periods that establish 10-year monopolies on product sales, the manufacturer is theoretically required to produce evidence of a product's safety and effectiveness. I say theoretically because, as will be discussed below, existing standards of safety are not enforced.

Note that the manufacturer is not required under federal pesticide law to show the "essentially" of introducing yet another toxin into our homes, food or workplace. Yes, Mr. Chairman, we are terribly concerned about a knee-jerk chemical response to pest problems when there often exist alternatives which are safer, less costly, and let me stress, more effective. For example, the Congressional Office of Technology Assessment, in a 1980 report, said an integrated pest management (IPM) approach, which utilizes a mixture of pesticides, natural predators and biological controls, can for major U.S. crops, "reduce pesticide (use) up to 75%, reduce preharvest pest-caused losses by 50% and reduce the total pest control costs by a significant amount."

The fact is, the public is faced with an increasing number of pesticide products on the market. From 1950 to 1970, overall pesticide production increased from 200,000 pounds to 1.4 billion pounds.[1] For the public to be concerned about the safe use of these products is natural. For Congress to ensure that these products are safe is imperative.

Communities that no longer have safe drinking water because their ground water is contaminated with pesticides do not accept continued Congressional inaction in this area. Neither do people in towns where herbicides, once used in Vietnam, drift. Neither do people consuming beef or fish that show suprisingly high levels of dioxin, perhaps the most deadly chemical contaminant known to the human race. Neither do millions of homeowners across this land who, given the construction of their homes, may have inadvertently poisoned their families when treating for termites. Neither do farmers and farmworkers of our country who go to bed sick and suffer chronic health problems associated with pesticides. Neither do unborn and newborn children whose exposure to contaminants jeopardizes their future health.

Mr. Chairman, the numbers of people, the numbers of communities and the number of problems add up. The problems are not new. There are just a growing number annually. As time passes, there is yet additional documentation which indicates that these problems reflect a regulatory control program that is not working.

Our overriding concern, then, relates to whether the public and workers of our country and those receiving products produced in the U.S. and sold outside our borders, are adequately protected from exposure to dangerous, potentially life-threatening, pesticides. The answer, Mr. Chairman, is a resounding no.

I would like to share with you and the Subcommittee how we go about answering this question in some detail. We start by looking at the state of pesticide safety and effectiveness in this country. The remainder of my testimony will:

1. Outline the pesticide problem as we see it;
2. Describe the current regulatory and statutory failure to control pesticides, and;
3. Propose a preventive approach and legislative proposals to protect the public.

THE PESTICIDE PROBLEM IN REVIEW

The need to improve federal pesticide law grows out of the long list of disturbing events which we attribute to pesticide use and misuse. IGNORING THESE SIGNALS NOW WILL ONLY COST OUR NATION MORE LATER.

We have seen crop damage, fish, bird and bee kills, contaminated drinking water, poisoned food, contaminated homes and sickness. At the same time, product effectiveness appears to be waning and insect and weed resistance to these chemicals are on the rise. Insect resistance is reported in nearly 400 species and farmers are reporting weed resistance to herbicides.[2]

Health

Just as EPA shut down its Pesticide Incident Monitoring System (PIMS), which tracked rates of poisonings and other pesticide-related problems, the only state with a reporting system of its own, California, saw a 27 percent increase in poisoning in 1982 and a 78 percent increase in the number of days poison victims required hospital care.

According to EPA estimates, a total of 45,000 people are treated for pesticide poisoning annually. The National Study of Hospital Admitted Pesticide Poisonings estimates 3,000 cases of hospital-admitted pesticide poisonings yearly with a 25 percent and 35 percent increase for farmers and farmworkers, respectively, over the last decade.[3] A Medical University of South Carolina study concludes that for every hospital-admitted case a physician treats 15 office cases. We believe these figures to be extremely low due to the fact that there does not exist in this country a mandatory pesticide reporting system. In fact, we believe that actual harm attributed to pesticides to be closer to the figures presented by the U.S. Department of Health, Education, and Welfare in 1970: 800 persons killed and 800,000 injured annually as a result of pesticides.[4]

The chemical industry recognizes the health problems associated with pesticide use and misuse. At their annual meeting in 1980, the president of the National Agricultural Chemicals Association (NACA) said, "In my judgement, involuntary exposure (to pesticides) is becoming the central public health issue of the 1980's."

The January, 1981 report Chemical Hazards to Human Reproduction, issued by the Council on Environmental Quality, cites various studies of male and female workers exposed to pesticides. These studies report impotence, chromosome aberrations, infertility, miscarriages and other adverse effects on reproduction.

A University of Iowa study of farmers in that state found that six types of cancer pose greater risks to that population group than to city dwellers. According to the researchers, the cancer rate is an occupational hazard of farming not related to smoking.[5]

Pesticides are turning up in wildlife, milk and in the nation's groundwater in case after case. Recently, North Carolina, Montana, Hawaii, Wisconsin, New York, Maine, Florida and California have had to face questions of pesticide contamination of their food and water supply.

Economic and Social Costs

While the magnitude of health problems due to pesticide exposure grows, some say in epidemic proportions, many researchers are calling attention to the diminishing returns associated with chemical pest management. As mentioned above, pesticide resistance has been reported in nearly 400 insect species. And while the response may be to increase the dosages and potency of the pesticides, insects appear to be fighting back with tremendous resiliency. Insecticide use has increased eleven-fold in the last thirty years, while crop loss due to insect resistance has doubled.

It has been estimated that it costs our nation $135 million in losses to the honey bee industry due to poisoning and reduced pollination every year. All told, researchers have estimated that pesticides now cost our nation $839 million annually in losses attributed to environmental and social costs. Preliminary results include: $184 million in human pesticide poisonings; $12 million in livestock losses; $287 million in reduced natural enemies and pesticide resistance; $135 million in honey bee poisonings and reduced pollination; $70 million in losses of crops and trees; $11 million in fish and wildlife losses, and $140 million in miscellaneous losses such as government costs to respond to pesticide problems.[6]

FAILURE OF THE REGULATORY AND STATUTORY PESTICIDE CONTROLS

On the basis of the dimensions of health and environmental problems alone, Congress should move expeditiously to chart an improved program of public and environmental protection. However, the definition of the pesticide problem is far larger than a discussion of the health, environmental and economic effects of pesticide use. A close look at EPA's pesticide program and limitations in our national pesticide law illustrate the need for immediate statutory remedies.

Lack of Health and Safety Data

Important information has recently been documented by a Staff Report on the EPA Pesticide Regulatory Program, produced by the House Agriculture Subcommittee on Department Operations, Research and Foreign Agriculture. One of the most serious findings of the report is the extent of missing health and safety data for pesticide products registered by the EPA.

EPA simply does not have data for most products' ability to cause cancer, genetic damage and birth defects. Using data from EPA's files, the Staff Report reveals discomforting figures indicating:

- between 79 and 84 percent of the products on the market have not been adequately tested for their capacity to cause cancer;
- between 90 and 93 percent of the same products have not been adequately tested for their ability to cause genetic damage;
- between 60 and 70 percent have not been fully tested for their ability to cause birth defects, and;
- between 30 and 46 percent have not been fully tested for reproductive effects.[7]

Congress has been aware of this problem, to some extent, since 1980 when the U.S. General Accounting Office published its report, Delays and Unresolved Issues Plague New Pesticide Protection Programs. The report states,

> [A]ccording to EPA officials, key tests required under current EPA regulations have not been performed for many of the 514 registration standards pesticides. Included are long-term (up to 3 years) animal feeding studies which show whether a pesticide causes chronic effects, such as cancer or birth defects, in animals. An official told us that EPA needs the results of these tests to make even preliminary decisions concerning a pesticide's safety and whether it should be reregistered.[8]

Faulty Data

Furthermore, EPA, for years, has been accepting faulty health and environmental test data on pesticide products now on the market. One of the largest falsifiers of data, the Industrial Bio-Test Laboratories, Inc. (IBT), provided EPA with hundreds of chemical safety tests to support the registration of nearly 200 products. In a recently released report, EPA has verified that only 3 percent of the IBT data submitted in support of registration is valid.[9] Unfortunately, IBT is not an anomaly. Investigative reports indicate widespread problems with testing laboratory practices.

Canada, faced with the same faulty data situation as the U.S., has banned or restricted 6 IBT chemicals while our country has taken no such action. In fact, EPA officials maintain that the law prohibits taking action similar to Canada without "valid evidence of risk, as opposed to a lack of information." As a result, products remain on the market with invalid tests supporting their registration until such time as EPA can show environmental harm. To the contrary, the Director of the California Department of Food and Agriculture is required to cancel a pesticide registration when "the applicant has submitted inaccurate or incomplete information." [3 Cal. Admin. Code §2360(d)]

Lab Audit Program

EPA was apprised of the inadequacy of lab testing as early as 1976 in a scientific review of chronic rat studies for 23 pesticides. In a report to the Office of Pesticide Programs, Melvin Reuber, M.D. said, "There was inadequate presentation, tabulation and analysis of data and often there were insufficient data included to make an accurate analysis possible. . . .Data presented in several tables were misleading or distorted. . . .Confirmation of the summary data by examination of the raw data was not easy."[10]

Despite the extensive problems with lab practices and even though EPA has audited nearly 100 testing labs since it began its lab audit program in 1977, questionable lab practices continue. EPA lab audits indicate, for example, the following:

> Bio/Dynamics - The audits revealed serious concerns about the reporting of tumors, the supervisory controls, the monitoring of environmental conditions and the timeliness of post-mortem examinations, among others.
>
> Biosafety Research Laboratory - These studies were invalidated by agency reviews on the basis of unclear dose determination and lack of proper animal examinations.
>
> Biospherics - Method evaluated is not adequate for regulatory purposes.[11]

According to a report in the San Jose Mercury, March 6, 1983, "None of the most suspect labs has been audited again. And despite the questionable value of some of the studies, not one pesticide registration has been withdrawn."

The House Staff Report concludes, "Except for the IBT case (which occurred before the audit program began), there is no solid indication, however, that any decisive regulatory or enforcement actions have been taken as a result of the laboratory audit program."[12]

Conditional Registration

The federal pesticide control law allows "conditional registration" of new products even though the data base may not meet the requirements for registration because of faulty or missing data. In addition, registrants can bring a product to market with conditional status if it is similar to one registered prior to 1975 with much less stringent requirements. In the name of "fair play," the law allows similar or identical untested products on the market. What we see, then, is a proliferation of untested products with unknown risks. All EPA requires is that, "All registrants of like products will have to provide missing data at a time specified in the future."[13]

Special Local Need and Emergency Exemption Permits

Unbeknownst to the public, a pesticide may be in use under one of a number of increasing "special local need" or "emergency exemption" permits. In the four year period between 1978 and 1982, the issuance of emergency exemptions under the "specific," "crisis," and "other" categories rose from 149 in FY 1978 to 673 in FY 1982; a 352 percent increase. From FY 1976 to FY 1982, the number of "special local need" registrations issued jumped 1,216, from 440 to 1,656.

The concern about the rising numbers grows out of the Staff Report's and our own information about these types of registrations. According to the Staff Report,

> Pesticide registrations granted through Section 18 ("emergency exemption") and 24(c) ("special local need") almost always entail significantly less complete and rigorous data requirements and scientific reviews.
>
> Possible serious adverse effects on the environment and wildlife may occur as a result of uses registered under Section 18 and 24(c) during the sometimes extended period during which

> EPA analyzes the potential impacts associated with pending Section 3 applications for similar uses.

A study released last week by the Rural Advancement Fund of the National Sharecroppers Fund outlines the dramatic nature of the problem. Using a sample of 2,089 special local need (SLN) registrations for 25 states (79 percent of all SLNs granted in 1981-1982), RAF/NSF found that:

- more than 40 percent of all SLN pesticides registered in the past two years contain chemicals registered on the basis of invalid or fraudulent tests conducted by IBT. For example, IBT conducted the safety tests for the three most widely used SLN pesticides (Furadan, Sencor, Paraquat). These products received a total of 361 SLNs in 25 states in 1981-82.
- a majority of the SLN registrations were issued for major crop use over a wide geographic area. More than 60 percent of all SLNs were issued for use on ten major crops.
- 90 percent of the registrations are obtained by chemical manufacturers. Five companies received 46 percent of all SLNs in 1981-82.[14]

Tolerances and Food and Feed Products

The 1980 GAO report, Delays and Unresolved Issues Plague New Pesticide Protection Program, indicates that there exists a severe deficiency in the tolerance setting program at EPA. The report reads,

> Our 1975 report to Congress stated that the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies. The situation has not improved. During our current review, an EPA official told us that the basis for many tolerances granted by the Food and Drug Administration is still obscure. According to the official, little, if any, documentation exists explaining how or why these tolerances were granted. Additionally, the Assistant Administrator for Pesticides and Toxic Substances stated that not much difference exists between the present condition of EPA's test data files and those that existed at the time of our 1975 report.[15]

Furthermore, many of the chemicals registered with IBT data have received food tolerance levels based on invalid information which has not been replaced with valid tests. As a result, the Agency offers the public no assurance that pesticide residue levels set for hundreds of products do not pose a health risk.

Despite the fact that the fungicide Captan was under review for exceeding risk criteria, including potential mutagenic effects, and was known to have been registered with IBT data, EPA, in 1981,modified a tolerance to allow corn seed coated with the chemical to be fed to hogs and beef cattle destined for the American dinner table.

Indoor Air Pollution

The use of insecticides chlordane, aldrin and lindane (all belonging to a class of pesticides called organochlorines, which includes DDT) for termite control has attracted a lot of public attention because of the widespread contamination of possibly millions of homes. This occurs despite the fact that these chemicals have limited uses. Many exposed to small levels of these chemicals have suffered headaches, muscle aches, nausea, sleeplessness and excitability. More severe illnesses, such as convulsions, loss of consciousness, disorientation, personality changes, psychic disturbances, loss of memory and a variety of blood diseases , are associated with high exposure levels. It is not uncommon for those in a contaminated home to live with a constant fear of the long term chemical effects.

In the case of chlordane, the National Academy of Sciences has recommended a "safe" level to be no more than five micrograms per cubic meter of air. Chlordane has caused cancer in the liver of mice and is a suspected human carcinogen.

However, no chlordane or other organochlorine residual levels in homes are currently set to protect the public health. In a January 17, 1983 letter explaining federal policy, former Deputy EPA Administrator, John Hernandez, said the setting of maximum residual levels or tolerances for pesticides with indoor uses is outside the Agency's legal authority. He states, "Neither the Federal Food, Drug and Cosmetic Act, the FIFRA, nor any other pertinent statutes, provide for setting tolerances for residues of pesticides in air or on surfaces in buildings."

When federal law and EPA have been negligent, those damaged by pesticides are forced to seek after-the-fact restitution.

On a case by case basis we are beginning to see a system of control set up locally which should be afforded the general public rather than established through costly litigation. A judge in Los Angeles, California, after ruling against a local extermination company, ordered a detailed training program for pest applicators and notice to all future customers of the type of chemical being utilized, the restrictions on application, type of symptoms caused by overexposure and telephone numbers for assistance should a problem arise.

"Intra-State" Pesticide Registration

EPA and Congress have allowed the continued use of pesticides that are sold in interstate commerce but not registered with the federal government and therefore out of compliance with safety standards. The EPA has used its discretion under the intra-state registration program to leave on the shelves thousands of products which were on the market prior to August, 1975 without safety studies. Estimates of pesticides in this category range from 3,000 to 6,500.

This circumvention of all standards of safety is graphically depicted by the continued state approved uses of Compound 1080 (Sodium Monofluoroacetate) for rodent control while federal restrictions have been in place over the last decade. According to EPA, only one Compound 1080 product is federally registered and can only be used by bonded professional applicators for control of the Norway rat, roof rat, and house mouse in buildings, ships, warehouses ahd homes. On the contrary, there are 50 products which have intra-state registrations for control of a variety of other rodents on rangeland, pastureland, and cropland. In fact, 95 percent of all 1080 rodenticide uses are based on intra-state registrations. These state approved uses continue for Compound 1080, as do thousands of others, despite questions of safety and the lack of any residue data.

In addition to the question of the adequacy of product safety tests for products with intra-state registrations, these pesticide products may not have

- adequate precautionary statements on the label;
- adequate use directions, and;
- percentage ingredients, including active ingredients, listed on the label.

Product Efficacy Information is Lacking

Beyond questions of safety supporting a pesticide product's registration, the pesticide user and the public have no real assurance that the product will perform as the manufacturers claim.

EPA explains efficacy requirements under FIFRA in the Federal Register of November 24, 1982 where the Agency proposes to further reduce the efficacy data required for registration.

> Those products for which an efficacy data requirement was continued in 1979 were products which, if they lack efficacy, could potentially have significant public health effects, such as mosquito control products, rodenticides, certain other invertebrate and vertebrate control agents, and antimicrobial products. The Agency now be-

> lieves that because many of the "public health" use patterns identified at the time are more of an aesthetic and nuisance problem than one of public health and are in any case adequately covered by other regulatory mechanisms offering assurance that the products are efficacious, and because the efficacy of products for other of these uses are adequately discernible by the user, marketing of inefficacious products is unlikely.
>
> The Agency is proposing to extend its current waiver to efficacy data for all uses of pesticides except those where control cannot reasonably be observed or determined by the user and lack of control is a clear adverse health effect.[16]

EPA, under FIFRA, has waived most efficacy data believing that users are protected since "pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use." However, this kind of statement does not provide much consolation for farmers like those in Kennewick, Washington, who, after investing in herbicides they allege to be inefficacious, are now seeking legal action against some chemical manufacturers.

In addition to the potential economic harm suffered by farmers, Dr. Stephen Frantz, a public health official with the New York State Department of Health, says that the consequences are of public health significance, but the effects are generally of a chronic nature rather than acute." Dr. Frantz continues,

> There have been problems with efficacy of rodenticides as well as other products as evidenced by EPA's own testing laboratory at Beltsville (D. Peacock and S. Palmateer, 1979, "Comparison of EPA Animal Biology Laboratory and Company Laboratory Efficacy Data for Federally Registered Rat and Mouse Baits"). Most products passed by companies failed when tested by EPA for registration purposes.[17]

Poor Training of Pesticide Applicators

The July 1, 1983 GAO review of the joint federal-state program for certifying and training individuals to apply pesticides indicates that "certification examinations do not fully conform to the Federal requirements and as a result do not provide assurance of an individual's competency."[18] The pesticide training and certification program is an important program from the standpoint of numbers alone. More than 1.5 million individuals have been certified since the program's inception in 1978. The program becomes more important when we consider the problems associated with over application, lack of safety precautions, and improper mixing, loading and storage of chemicals.

The GAO report notes that since 1976 the EPA's Region V office has not performed any substantive reviews of Illinois and Minnesota commercial applicator examinations "to ensure compliance with Federal standards." Officials admit that their twice a year reviews are "superficial at best."

Beyond not ensuring examination compliance, the report states that EPA "has not completely reviewed test quality despite questioning some state examinations." In fact, GAO found that many test questions are self-evident to people without any pest control knowledge, such as one true-false question which asks if insecticides are used for insect control. In conclusion, GAO says, "Specific criteria to regional offices have generally not assessed state certification tests for compliance with Federal requirements and adequacy for demonstrating competency because they were never provided with criteria for doing so."[19]

In addition to what can be characterized as inadequate training for those handling toxic chemicals, the federal law requires no proof of certification to purchase the most restricted class of pesticides, the restricted use category. Moreover, a clear loophole in the law allows untrained people to apply restricted use pesticides "under the supervision" of certified applicators. This clause is not defined and clearly not enforced.

The GAO report stresses that states, which carry out the federal training program, are not addressing major pesticide misuse problems because they "are not routinely and systematically gathering, analyzing and summarizing pesticide misuse information such as the number and type of misuse violations, the underlying causes of misuse, the circumstances surrounding the misuse and the types of violators."[20]

Poor Enforcement of the Law

From an enforcement perspective, an October, 1981 GAO report, entitled Stronger Enforcement Needed Against the Misuse of Pesticides, suggests that the public and the environment are not protected from pesticide misuse because EPA and state enforcement programs exhibit the following characteristics:

- Many enforcement actions are questionable or inconsistent;
- Some cases are poorly investigated;
- Some (state) lead agencies often do not

share EPA enforcement philosophy, and;

- Most States lack the ability to impose civil penalties.[21]

A comparison with the enforcement of other federal laws is very instructive. During Fiscal Year 1981, EPA assessed only $123,473 in civil penalties under FIFRA. In comparison, under the Clean Water Act nearly $3 million in civil penalties were assessed and over $9 million in civil penalties were assessed under the Clean Air Act. In addition, cases referred to the Department of Justice under FIFRA fall far below referrals under the Clean Water Act.

CREATING A PREVENTIVE APPROACH AND ADOPTING LEGISLATIVE REMEDIES

Seeking a Preventive Approach Which Assures the Public Right to Know

Rather than face crisis after crisis, we seek a preventive approach to the pesticide problem. We would like to minimize health and environmental damage and therefore are calling for a more rigorous program of pesticide registration.

Our national pesticide policy, or lack thereof, is helping us to dig ourselves into a social and moral dilemma so deep that we may not be able to climb out. The recent EPA action on toxaphene, an insecticide with widespread uses, is a case in point which raises the ultimate question of whether we can really clean up after our mistakes.

In May of 1977, EPA issued a "Notice of Rebuttable Presumption Against Registration and Continued Registration of

Pesticide Products Containing Toxaphene." In November, 1982, over five years later, EPA finds without equivocation that,

> [T]oxaphene induces cancer in laboratory animals and is acutely and chronically toxic to aquatic life and birds (including endangered species). Examination of the patterns of use and the potential for exposure indicates that toxaphene is extremely persistent, moves readily through the environment, and contaminates habitats of vulnerable aquatic avian species at levels sufficient to reduce their populations, and that humans are exposed to toxaphene through occupational contact and contamination of a range of food products, particularly fish. The potential risks to wildlife and human health resulting from toxaphene exposure were found to be extremely high.[22]

The public is then told by EPA that this chemical's use for scabies treatment of beef cattle and sheep are retained, as are several minor uses, including application to bananas and pineapples in Puerto Rico and the Virgin Islands. Reading the EPA notice further reveals that a more complicated regulatory scheme is established to allow the continued use of existing toxaphene stocks until 1986. The same chemical EPA has found to accumulate in our food chain has received the following limitation on further use.

> Existing stocks of toxaphene may be used for for specified periods of time under very limited terms and conditions partly because such use is judged to be the most desirable means of achieving disposal of those stocks.[23]

The point here is that EPA really has no satisfactory solution to a problem it has finally identified. The Agency has merely identified a "most desirable" solution. EPA's own staff has said that there is so much existing stock (several million pounds) that toxic waste dumps would be unable to adequately dispose of the volume safely. The Agency conclusion: It would be preferrable to disperse the pesticide at low doses in the environment.

The risks of this and other chemicals continue in a cloud of secrecy as the chemical industry seeks to prohibit public disclosure of the health, safety and environmental effects data used to register pesticide products. Scientific methods and data used to register pesticide products should be subjected to formal and full scientific review. This open peer review through the traditional method of publishing in scientific journals accomplishes two key objectives. It assures:

1. Informed public and worker decision making on pesticide product use and exposure, and;
2. Improved EPA effectiveness by minimizing problems and biases that may be in health and environmental studies which have been submitted to EPA.

Informed public choice is a constitutional right. As cited in the Harvard Law Review, March, 1980, and in the courts,

> [I]t is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its policy power and in promotion of fair dealing, to require that the nature of the product be fairly set forth.[24]

The chemical industry has challenged the constitutionality of sharing health, safety and environmental testing data with the public on the grounds that it robs them of their proprietary interests. While this argument has been rejected in most courts of law since 1978, the industry position prevailed in a April, 1983 District Court ruling (Monsanto vs. Acting Administrator, U.S. Environmental Protection Agency). The government has appealed this recent judgement to the Supreme Court.

Throughout the debate on the question of data disclosure, the chemical industry lobby has produced no studies of the likelihood that disclosure of health and safety data would cause competitve harm, particularly overseas as has been claimed. Thomas McGarity, of the University of Texas School of Law, maintains, "The burden should be upon the pesticide industry to demonstrate why the speculative possibility of lost profits in foreign markets warrants measures that would significantly impede public access to health and safety studies concerning chemicals to which humans and the environment are daily exposed."[25]

Legislative Remedies for the Pesticide Problem

A coalition of Senate and House members is organizing to introduce legislation this session which would improve the public health and environmental protections from pesticide hazards. Proposed legislation seeks to assure:

- a more protective pesticide registration program at EPA by closing numerous loopholes in the current law which allow safety standards to be circumvented;
- improved protection for humans exposed to pesticides, with particular emphasis given to those handling chemicals, those working on the farm

and children;

- adequate enforcement of federal law and legal remedies for those who have been damaged by pesticides by creating a private right of action or citizen suit provision;
- public participation in pesticide decision making at EPA so that all the facts can be brought to bear before a registration decision is made as well as after an application is granted, and;
- products are tested for effectiveness to ensure that chemicals perform as the manufacturers claim.

CONCLUSION

Mr. Chairman, we appear here today on behalf of the thousands of individuals who have fallen victim to a system of pesticide control that is not working. These are people who face exposure problems that are frustrating. They seek answers and find none. They call government agencies for assistance and tell us that they find little satisfaction.

These are the same people who have been told that most of what we have learned about chemicals, like toxaphene, was not known when the chemicals were first introduced. We have been told this about dioxin, although early 1965 industry memos have since refuted unequivocal claims of safety.

Mr. Chairman, you and this subcommittee have an opportunity to lead our nation in establishing a more cautious national pesticide policy, to take precautions and to seek answers before problems occur. You can choose this responsible course or choose to tell another generation that we just did not know.

RESOURCES

[1] Samuel Epstein, The Politics of Cancer, New York: Anchor Press, 1979, p. 248 (compiled from statistics of the U.S. Department of Agriculture, 1979).

[2] Dale Bottrell, Integrated Pest Management, Council on Environmental Quality, December, 1979, p. 9.

[3] U.S. Environmental Protection Agency, National Study of Hospital Admitted Pesticide Poisonings, 1976.

[4] Senate Report No. 91-1282, 91st Congress, 2nd Session; reprinted in U.S. Code Cong. and Adm. News (1970), pp. 5179-5180.

[5] Leon Burmeister, "Cancer Mortality in Iowa Farmers, 1971-78," JNCI, Vol. 66, No. 3, March, 1981, pp. 461-464.

[6] David Pimentel, et. al., "Environmental and Social Costs of Pesticides: A Preliminary Assessment," Copenhagen: OIKOS, 34: 126-140 (1980), p. 135.

[7] Staff Report, EPA Pesticide Regulatory Study, Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives, 97th Cong., 2nd Session, December 17, 1982, p. 187.

[8] U.S. General Accounting Office, Delays and Unresolved Issues Plague New Pesticide Protection Programs, CED-80-32, February, 15, 1980, p. 15.

[9] U.S. Environmental Protection Agency, Office of Pesticide Programs, Summary of IBT Review Program, July, 1983.

[10] Melvin D. Reuber, M.D., "Review of Toxicity Test Results Submitted in Support of Pesticide Tolerance Petitions," The Science of the Total Environment, Amsterdam, 9(1977), pp. 135-148.

[11] U.S. Environmental Protection Agency, "Health Effects Data Quality Status Report," October 19, 1979, and Stephen Barlas, "EPA Slow to Clean Up Laboratories That Cheat," San Jose Mercury, March 6, 1983.

[12] Staff Report, p. 204.

[13] Edwin L. Johnson, Director, Office of Pesticide Programs, U.S. Environmental Protection Agency, Testimony before the Subcommittee on Agriculture, Research and General Legislation, Committee on Agriculture, Nutrition and Forestry, U.S. Senate, 98th Cong., 1st Session, May 24, 1983, p. 8.

[14] Allen Spalt, A Report on "Special Local Need" Pesticide Registrations, Rural Advancement Fund of the National Sharecroppers Fund, July 27, 1983.

[15] Delays and Unresolved Issues Plague New Pesticide Protection Programs, p. 19.

[16] 47 FR 53196, Pesticide Registration; Proposed Data Requirements, November 24, 1982.

[17] Dr. Stephen Frantz, Letter to EPA dated May 11, 1983 re. 40 CFR 158, Pesticide Registration; Proposed Data Requirements, pp. 1-2.

[18] U.S. General Accounting Office, Better Coordination Is Needed Between Pesticide Misuse Enforcement Programs and Programs For Certifying and Training Individuals To Apply Pesticides, RCED-83-169, July 1, 1983, p. 1.

[19] Ibid., pp. 11-12.

[20] Ibid., p. 7.

[21] U.S. General Accounting Office, Stronger Enforcement Needed Against the Misuse of Pesticides, CED-82-5, October 15, 1981, p. ii.

[22] 47 FR 53785, Intent to Cancel or Restrict Registrations of Pesticide Products Containing Toxaphene, November 29, 1982.

[23] Ibid.

[24] Thomas O. McGarity and Sidney A. Shapiro, "The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies," Harvard Law Review, March, 1980, Vol. 93, No. 5, p. 867.

[25] Thomas O. McGarity, Hearing on FIFRA --Pt. 1, Before the Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, 97th Cong., 2nd Session, p. 324.

Chamber of Commerce of the United States of America
Washington

STATEMENT
on
TOXIC SUBSTANCES CONTROL ACT (TSCA)
for submission to the
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT
of the
SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE
for the
CHAMBER OF COMMERCE OF THE UNITED STATES
by
Dr. Harvey Alter*
August 11, 1983

We appreciate the opportunity to express our members' concerns regarding reauthorization of the Toxic Substances Control Act (TSCA). The membership of the U.S. Chamber includes companies that manufacture, process, distribute and use chemicals to provide products and services ranging from the most common household chemical to the most sophisticated chemical intermediates and products for high technology industries. This array of companies, therefore, is sensitive to the direct and indirect effects of TSCA that may affect their ability to deliver goods and services to the public.

The Chamber supports TSCA as an effective means of protecting human health and the environment from abuse or insult by the misuse of chemical substances. Although TSCA is not yet fully implemented, there is ample proof that the major provisions can -- and are -- fulfilling their original intent. We are confident that in the near term the law will do even more and thus, see no reasons to seek any change in TSCA at this time. We propose that Congress reauthorize the continuation of the Act as it stands.

The basis for these observations and conclusions follow.

BACKGROUND

The Toxic Substances Control Act has been in effect for six years, which is almost the same period of time it took Congress to deliberate the complex issues concerning how chemicals -- the basic materials of life and nature -- should be regulated. When the law became effective in 1977, industry supported it and asked that it be administered in accord with the intent of Congress.

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*Manager, Resources and Environmental Quality Department, Chamber of Commerce of the United States.

The intent is expressed in Sec. 2 of TSCA, which recognized that there is no zero risk and calls for a balancing of potential risks with social-economic benefits. It requires administration in a reasonable and prudent manner so as not to impede innovation.

We believe that TSCA, as written, is a responsible piece of legislation and, when fully implemented, is capable of accomplishing its intended purposes.

EVIDENCE OF SUCCESS

It is worth summarizing some of the success to date of TSCA, how it is protecting health and environment in accord with the goals of Sec. 2. For example:

- Sec. 5 requires premanufacturing notification (PMN) before new substances can be produced for commerce or petitions to the Environmental Protection Agency (EPA) before such materials are even test marketed. To date, more than 2,000 PMNs on new substances have been submitted and reviewed by EPA. When there has been inadequate information to make evaluations, the Agency invoked Sec. 5(e) to require more testing. In instances where the PMN indicated a potential unreasonable risk, EPA did not approve the notification and so prevented commercialization, or it used Sec. 5(f) to place limits on manufacture or use. Appropriately, consideration is now also being given to rules under Sec. 5(h)(4) to exempt from PMN substances that present no unreasonable risk and so eliminate unnecessary burdens upon industry, the Agency and the taxpayer.

- In order to determine which existing chemicals should be further tested or controlled, most subsections of Sec. 8 have been activated. All existing commercial chemicals have been identified by manufacturer, location and volume using Sec. 8(b). Exposure in production and use information for a list of 250 substances was submitted by companies in response to a Sec. 8(a) rule. Additionally, health and safety studies were provided on another list of more than 300 chemicals to comply with a Sec. 8(d) regulation. Industry will also be submitting more data on these last two rules for other substances as an ongoing requirement. Finally, industry has submitted more than 470 substantial risk notifications to meet the obligations of Sec. 8(e).

- Under Sec. 4 priority testing, an Interagency Testing Committee has designated 73 substances and classes of substances. Action has been taken on 35 of these by the Agency. Industry testing initiatives and proposed rules arrived at by effective dialogue have hastened this process. A recent report by the General Accounting Office endorsed this approach to expedite testing.

- Control actions have been instituted by EPA on polychlorinated biphenyls (PCB's), chlorofluorocarbons and dioxins. The Agency has also defined a new evaluation and control procedure to which 48 materials are now being subjected. Companies will have to respond to restrictions imposed by regulations on any of these substances.

The above are requirements directly imposed by TSCA to which industry has responded or soon will be responding. In addition to these direct responses, there has been an equal or greater response by industy to indirect requirements imposed by TSCA.

VOLUNTARY RESPONSES AND INDIRECT BENEFITS OF TSCA

The passage of TSCA has caused a tremendous response of voluntary action by industry. In order to meet their obligations in a responsible manner, the affected industries have created a new TSCA-related infrastructure within the private sector. Special skills have been developed, directed toward the establishment of the human and environmental safety of chemical substances.

Industrial facilities and expertise in disciplines such as human- and eco-toxicology, aquatic biology, chemical pathology and teratology, are the rival of most countries. A visit to any chemical plant today will afford highly visible evidence of the extent to which direct and indirect requirements of TSCA are being responded to by industry. Some of the accomplishments are:

- o Management, production, marketing and research personnel devote efforts to compliance, or preparations for compliance, as part of their regular job descriptions and duties.
- o New lines of communication have been established and systems for data storage and retrieval provided.
- o Companies have stepped up voluntary testing through contract laboratories and larger companies have constructed and staffed their own toxicology and environmental testing labs.
- o Increased effort has been devoted to industrial hygiene monitoring, medical examinations and epidemiological studies.
- o Voluntary systems of hazard communications, labeling, awareness and training have been broadly instituted.
- o New precautionary procedures have been added, intensified use of protective equipment fostered, and greater engineering controls imposed.

CONCLUSIONS

The six years it took Congress to develop TSCA resulted in a set of integrated provisions and an overall stimulus to a new kind of awareness of product safety and environmental compatibility. From industy's perspective, the law is most assuredly working. We continue to support the law because we feel it is necessary to have uniform rules to prevent a few would-be offenders from seeking an unfair competitive advantage at the expense of human health and the environment.

In closing, we call attention to the fact that, in the early years, there was little real progress in implementing TSCA, mostly because this was a learning period. Consequently, many of the mandatory requirements of the law cited above have been imposed rather recently, based upon mutual understanding and experience. This has lead to a recognition, not only by industry and the Agency but also by public interest groups, that there is a need for more open communications in the regulation development process.

By this, we are not suggesting ever bypassing the law, only a better dialogue among all interested parties to smooth the way for the development and practice of regulatory procedures. We encourage Congress to do nothing to reverse this favorable trend.

On the basis of the history of development and recent progress made in the public and private sectors in implementing TSCA, we ask that Congress permit the current process and practice to continue. We see no need to change the law at this time and ask that Congress reauthorize TSCA without change. This is a rare request. Often it has been necessary for all affected parties to seek changes in an environmental law within a few years of passage, as a sort of mid-course correction. In the case of TSCA, experience is proving to be the best teacher of how to achieve the original intent of Congress for all Americans.

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United States Senate
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, D.C. 20510

June 7, 1983

Mr. Karl-Heinz Narjes
Member of the Commission of the
European Communities
Commission of the European Communities
200 rue de la Loi
1049 Brussels

Dear Mr. Narjes:

The Subcommittee on Toxic Substances and Environmental Oversight will begin hearings in July on the implementation of the Toxic Substances Control Act (TSCA). One issue the Subcommittee will address is the premanufacture notification program under section 5 of TSCA.

We are aware that the Commission of the European Communities is implementing a related program under your Sixth Amendment. We would like to invite you to submit, on behalf of the Commission, a description of the Sixth Admendment and a general discussion of the status of its implementation by member nations. It would be especially useful if your submission could discuss the important differences that you see between the Sixth Amendment and the TSCA programs, as well as any implications for trade harmony and protection of public health and the environment resulting from those differences.

Sincerely,

Max Baucus
Max Baucus
Ranking Minority Member
Subcommittee on Toxic
Substances and
Environmental Oversight

Dave Durenberger
Dave Durenberger
Chairman, Subcommittee on
Toxic Substances and
Environmental Oversight

KARL-HEINZ NARJES
MITGLIED DER KOMMISSION
DER EUROPÄISCHEN GEMEINSCHAFTEN

1049 BRÜSSEL, DEN
RUE DE LA LOI 200

20 July 1983

Ref : your letter of 7 June 1983.

Dear Senator Durenberger,

Enclosed is the statement which I am pleased to send to you on behalf of the Commission of the European Communities concerning the Council Directive 79/831/EEC (6th Amendment) on the notification of new chemical substances, and a comparison of certain key elements of this Directive with the premanufacturing notification system under the US Toxic Substances Control Act.

The Statement is divided into 3 parts : a factual description of the Directive, a discussion of major differences in the TSCA PMN system and the 6th Amendment, and a discussion of the implications of these differences for international trade and the environment.

I hope that you will find these comments useful for your understanding of the EC's chemicals control policies in relation to TSCA.

Let me repeat here, that the European Community welcomes this opportunity to foster the collaboration with the USA on chemicals control policies.

./..

Subcommittee on Toxic Substances and
Environmental Oversight
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

U.S.A.

For the attention of Mr. Dave Durenberger,
Chairman

We are convinced that many aspects of these policies can be dealt with most efficiently and effectively at the international level of policymaking. It is obvious that the European Community and the USA must continue to seek opportunities to harmonise our chemicals policies, because this ultimately will be for our mutual benefit.

Yours sincerely,

Encl.

STATEMENT TO THE

Subcommittee on Toxic Substances and Environmental Oversight
United States Senate Committee on Environment and Public Works

THE NEW CHEMICAL NOTIFICATION SYSTEMS OF THE COUNCIL DIRECTIVE 79/831/EEC OF THE EUROPEAN COMMUNITIES AND THE UNITED STATES TOXIC SUBSTANCES CONTROL ACT

- Brussels, 15 July 1983 -

COMMISSION OF THE EUROPEAN COMMUNITIES

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Footnotes

Introduction

The Commission of the European Communities has been invited to provide information to the United States Senate Sub-Committee on Toxic Substances and Environmental Oversight. In particular, this statement covers three areas of concern to the Sub-Committee:

1. A general description of the major elements of Council Directive 79/831/EEC amending for the Sixth time the Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, and implementation by the Member States.

2. Important differences between the Toxic Substances Control Act and the 6th Amendment.

3. Implications for international trade, the chemical industries, and health and the environment resulting from these differences.

.../...

Summary

The 6th Amendment establishes a system for the testing and notification of new, industrial chemicals prior to their being placed on the market in the European Community.

The first, and all subsequent manufacturers or importers of a chemical substance defined as "new" and not falling under the defined exemptions must notify it to the appropriate national authority 45 days before marketing.

The notification must contain a technical dossier (Annex VII) which contains information about the chemical substance, its use, potential health and environmental risks, and safe disposal. The notification provides sufficient information for the Member States to monitor and, if necessary, regulate a specific chemical.

The 6th Amendment lays down a "step-sequence" system of testing which balances economic needs, administrative simplicity, and environmental protection by requiring more thorough testing for toxicity and ecotoxicity when certain marketing thresholds are reached. Provision is made for applying the higher testing and follow-up information requirements flexibly and in close consultation with the affected notifier.

The Directive protects information designated as confidential by the national competent authorities, while ensuring that certain basic data are available to the public.

Thus, the 6th Amendment encourages the unhindered marketing of new chemical substances in the European Community by establishing a single system to gather, exchange and update information about these chemicals among the Member States.

.../...

Despite the many fundamental elements shared by TSCA and the 6th Amendment, certain differences do exist. First and most notable is the content of the initial notification: while TSCA provides general authority and requirements for data to be submitted by the first notifier, the 6th Amendment lays down a detailed list of information which is in principle required in all cases and is considered sufficient to provide a cost-effective set of data for an initial assessment of the risk posed by a new substance.

Second, the 6th Amendment imposes a pre-marketing, not a pre-manufacturing notification requirement.

Third, the 6th Amendment provides for specific tests to be carried out at designated levels of marketing, in addition to more general follow-up reporting requirements.

Fourth, under the 6th Amendment a "new" chemical always remains a "new" chemical subject to the notification and follow-up reporting requirements for every producer or importer. The inventory of existing substances (EINECS) will be a static and final one.

Viewed most broadly, the 6th Amendment can be seen as a precisely defined system of gathering and exchanging information about chemical substances that are marketed in the European Community after a set date; it places primary responsibility for generating and evaluating the data on the chemical industry and primary responsibility for response on the governments of the Member States.

The 6th Amendment imposes a substantially greater initial information burden on the manufacturers of new chemical substances to generate data than does TSCA.

.../...

The information in the initial notification is consistent with the Minimum Pre-marketing Set of Data adopted by the OECD in 1982 and hence is compatible with the harmonised approach to the notification of chemicals being implemented by the OECD Member countries and envisaged elsewhere.

The extremely flexible approach adopted by the United States Environmental Protection Agency in implementing the Toxic Substances Control Act (in contrast to the 6th Amendment) has several negative consequences:

- far less information about potential hazards is supplied to the US Environmental Protection Agency. Thus, other governments may also be deprived of information which they may need if a chemical substance manufactured in the USA turns out to have potentially dangerous health or environmental effects;

- non-US chemical industries must face comparatively higher initial development costs compared to US industries;

- non-US companies may have comparatively greater difficulty knowing what information they must supply under TSCA because they are less familiar with the US government; such broad flexibility may offer opportunities for discrimination against individual foreign companies;

- resources of industry and government are not invested efficiently.

PART ONE - OVERVIEW OF THE 6TH AMENDMENT

The 6th Amendment (1) was adopted by the Council of the European Communities in 1979; it is so-called because it amended for the 6th time the 1967 Council Directive on the Classification, Labelling and Packaging of Dangerous Substances (2). It establishes a single "doorway" through which domestic manufacturers or importers may bring new chemical substances into the market of all Ten States of European Community by filing a proper notification solely in the Member State in which the chemical is first to be marketed or imported.

The 6th Amendment is a Council Directive; it was adopted by the Council of Ministers of the Member States (3). It defines precise objectives but must be implemented by national laws or regulations of each Member States. EC Directives may, on occasion, allow the Member States considerable leeway in deciding how the goals defined in a directive are to be achieved, but the 6th Amendment is quite precise. Uniformity of programs as well as goals is the heart of the matter. So, uniform implementation is the responsibility of the Member States, watched over and mediated by the Commission of the European Communities, and ultimately secured by the EC Court of Justice.

.../...

I. HISTORY AND PURPOSE

The 3 main goals of the 6th Amendment are:

- to provide adequate protection for people and the environment from the potentially harmful effects of chemical substances;

- to establish uniform notification procedures and requirements that are practical and enforceable; and,

- to protect the viability of the European chemical industries, and even to facilitate trade within the Community by avoiding technical barriers to trade.

The goal of preventing technical barriers to trade from arising from individual,national notification programs was a major impetus from the start. The Commission first proposed the Directive in 1976, basing it on Article 100 of the Treaty of Rome, which concerns the approximation of regulations and administrative action in the Member States that "directly affect the functioning of the Common Market".

Many factors needed to be taken into account in preparing a Community-wide notification system that would respect the different economies, societies, and political systems of the EC countries. The individuals involved in the consultations and negotiations were at the same time drawing on the USA's experience in implementing the Toxic Substances Control Act, and on the work of the OECD's Chemicals Programme (4).

The notification system foresees that each producer or importer of a new chemical will submit to the national competent authority an initial file containing a technical dossier of information about the chemical's identity, physico-chemical characteristics, toxicological and ecotoxicological effects, use,safe disposal and a risk assessment.

Further information about health and environmental hazards must be submitted when threshold levels of marketing are reached or if the national competent authority considers it necessary based on the results of its initial assessment.

II. SCOPE

The notification system applies to new chemical substances placed on the EC market after 18 September 1981. It excludes chemical substances that are already regulated equally or more stringently by the EC, such as pesticides, medicines, narcotics, radioactive substances, and dangerous wastes (Article 1).

Existing chemical substances are not subject to notification. They are substances which were on the EC market between 1 January 1970 and 18 September 1979, and will be included in the EC inventory.

The EC Inventory is being established according to the procedure provided in Commission Decision 81/437/EEC of 11 May 1981. The European Core Inventory (ECOIN) listing 34,000 substances was published on 31 March 1982. Manufacturers and importers then had 9 months to report to the national Contact Points additional substances that were on the EEC market during the reference period. The reporting period ended on 31 December 1983.

The Commission now is processing these declarations of additional existing substances. Publication of the European Inventory of Existing Commercial Chemical Substances (EINECS) is foreseen for 1985.

.../...

III. ALLOCATION OF RESPONSIBILITIES

1. The chemical industries

Of course, the 6th Amendment does not modify the ultimate legal responsibility of the chemical industries for the quality and safety of their products. It introduces the task of preparing and submitting a proper notification to the competent authority of the Member State in which a new chemical substance is first manufactured or imported.

a) Who must notify

The obligation to notify applies to any EC manufacturer or importer who puts a "new" chemical on the market in the European Community; that is, one which the notifier has not previously marketed.

b) What must be notified

Any chemical substance not specifically exempted, which had not been on the market in the EC between 1 January 1971 and 18 September 1981 must be notified. This means any chemical substance that is not on the inventory of existing substances (EINECS) to be established by the Commission and is not otherwise exempted.

c) When to notify

A new chemical in the European Community must be notified at least 45 days before being placed on the market (Art. 6).

.../...

d) Exemptions

Certain chemical substances described in Article 8 may be considered as having been notified under the Directive. They include chemicals marketed in quantities less than 1 ton per year, polymers containing less than 2 % of a new monomer, and chemicals undergoing research under conditions described in the Directive (Art. 8).

A limited announcement to the national competent authority must be made for chemicals placed on the market under 1 ton per year. The research exemption is limited to 1 year. The announcement must contain the chemical identity, labelling data, and quantity marketed, and the Member States may impose further conditions.

e) To whom the substance must be notified

The chemical substance must be notified to the competent authority in the EC country in which it is first imported or manufactured and placed on the market.

f) "Placing on the market"

Unlike TSCA, the 6th Amendment links the notification requirement to the marketing of a chemical, not to the manufacture. This is defined as "supplying or making available to third parties" (Art. 2(1)(e)).

g) The contents of the initial notification

The notifier must submit to the competent authority a file (Art. 6) which contains 4 items:

.../...

- a technical dossier (Annex VII) supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for people or the environment;

- a declaration about the unfavorable effects of the substance in terms of the various uses foreseen;

- the proposed classification and labelling;

- the proposals for any recommended precautions about the safe use of the substance (Art. 3 (6)).

Annex VII defines the specific information required in the technical dossier (see table p. 29) which is intended to provide the basis for an initial assessment of the potential hazards posed by a substance.

h) Follow-up information and further testing

Further testing for health and environmental effects as detailed in Annex VIII are required when the marketing level reaches 100 tons per year or 500 tons total (Level 1).

Still more rigorous testing is required when the marketing level reaches 1,000 tons per year or 5,000 tons total (Level 2). (See more detailed discussion below, p. 10).

The notifier must provide follow-up information beyond the base set to the national competent authority under certain conditions before the production levels triggering further testing under Annex VIII are reached (Art. 6 (4)).

.../...

In particular, the notifier must inform about:

- changes in the annual or total quantities placed on the market beginning at 1 ton, 10 tons, 50 tons, and so on;
- new knowledge of the effects of the substance on people or the environment of which the notifier may reasonably be expected to have become aware;
- new uses of the substance under Annex VII, of which the notifier reasonably may be expected to have become aware; and,
- any change in the properties resulting from a modification of the substance as described in Annex VII (1.3). (Article 6 (4)).

2. The competent authorities of the Member States

The competent authority in each Member State is responsible for receiving the notifications.

First, it must examine the notification for conformity with the Directive.

Then, it reviews the testing methods and good laboratory practice requirements. Any adaptation or omission of information will be examined for adequate justification.

Claims of confidentiality will be examined for conformity with the Directive and decided.

.../...

The competent authority may ask for further information or verification tests (including accelerated testing under Annex VIII) carry out sampling necessary for control, or regulate the use of the substance before Community regulations are adopted (Art. 6 (4), Art. 23).

The Commission will send a copy of the notification dossier or a summary to the other nine competent authorities (Art.s 9,10). They may consult with the competent authority that received the original notification or with the Commission about the data; they may also suggest that further testing be required (Art. 10 (2)).

A Member State may control or prohibit the sale of a notified substance in its territory if it has detailed evidence that the substance is hazardous to health or the environment (Art. 23). Such an action immediately triggers a consultation procedure among the Commission and the Member States designed to lead to a common approach for the entire European Community (Art. 21).

3. The Commission of the European Communities

The 6th Amendment assigns several key functions to the Commission concerning the transfer of information, enforcement, and resolution of potential conflicts (Art.s 9, 10 and 21).

Broadly speaking, the Commission's overall task is the harmonization of the administration of the Directive by:

- drawing up the inventory of existing chemicals (EINECS);

- preparing the list of new notified substances (Art. 13);

- determining physico-chemical, toxicological and ecotoxicological test methods, in consultation with the special Committee for Adaptation to Technical Progress, (Art.s 19, 20 and 21);

- developing guides for the omission from, substitution for, or addition to the tests required by Annex VII; and,

- establishing detailed guidelines for classification and labelling (Annex VI).

The Directive provides a decisionmaking procedure by which the Commission can ensure that national administrative practices and standards are in close harmony with each other (Art. 21).

IV. THE STEP-SEQUENCE SYSTEM OF TESTING

The information system on new chemicals established by the 6th Amendment creates a series of "safety nets" that link increasingly detailed testing with the volume of a chemical substance placed on the Community market. Because the notification applies to each manufacturer or importer of a new substance, these information "safety nets" provide for a continuing surveillance of new chemicals in the environment.

1. The "base set" and the technical dossier of Annex VII

The technical dossier described by Annex VII is designed to "supply the information necessary to evaluate the foreseeable immediate or deferred risks which the new substance may entail" for people or the environment.

Under normal conditions,the "base set" operates as a screening device for health and environmental hazards.

For example, information about physico-chemical properties is not only relevant to the identification of the substance, but also to the evaluation of the potential exposure of people and the environment to the substance. This information helps the competent authorities to predict the environmental distribution of a substance through degradation and metabolic processes and its accumulation in specific sectors of the environment.

The toxicological and ecotoxicological studies provide indications of the substance's potential adverse effects in biological systems, and were chosen for their usefulness in predicting potential hazards to human health and the environment.

.../...

2. Follow-up information and further testing

Further toxicological and ecotoxicological testing is required by Annex VIII when the marketing level reaches 100 tons per year or a total of 500 tons (Level 1). The tests take into account current knowledge of the substance, known and planned uses, and the results of the tests carried out in the base set.

If the quantity placed on the market reaches 1,000 tons per year or 5,000 tons total (Level 2), the notifier must inform the competent authority, which will draw up a program of tests to be carried out by the notifier in order to enable the competent authority to evaluate the risks of the substance for people and the environment.

The information that the notifier must give to the competent authority under Annex VIII, levels 1 and 2, should be sufficient to enable the authority to evaluate the chemical's potential hazard to the environment. These tests go further than the indicator tests in the base set and are designed to provide concrete indications of actual, as well as potential, environmental problems.

3. Flexibility; Test guidelines

The step-sequence system of testing is characterised by a fundamental flexibility, which ensures that implementation will keep pace with advances in scientific knowledge and administrative experience.

There are four aspects of this basic flexibility that keep Annexes VII and VIII from being rigid checklists of tests that must be carried out under all circumstances.

.../...

First, notifiers may omit information from the technical dossier if it is not technically possible or does not appear necessary, but they must be able to justify the omission to the national competent authority.

In principle, such omissions may be based on:

- the nature and properties of the substance,

- its behaviour; that is, its fate in the environment,

- its effects,

- the non-availability of adequate test methods.

Second is the flexibility in the choice of tests under Annex V. When several test methods for determining a single property are provided the notifier is free to choose the most appropriate one. The particular test may also be adapted - but not changed - to specific circumstances if this is explained and justified in the notification.

Third, the competent authorities benefit from a basic flexibility respecting their right to information from the notifier; they may ask for further information or verification tests concerning the substance, which may also include testing from Annex VIII before the marketing level triggers are reached.

The fourth element of flexibility concerns both the notifier and the competent authority, who must collaborate on defining the program of tests required under Annex VIII.

.../...

The information in the technical dossier and follow-up notifications must be based on methods recognized and recommended by competent international bodies. The test methods in Annex V were developed by the Commission of the European Communities with the help of experts from the Member States. They are closely modelled on the OECD Test Guidelines. The OECD Council actions on Good Laboratory Practice and Compliance with GLP will be incorporated into the 6th Amendment separately.

V. TREATMENT OF INFORMATION

An important issue during the preparation of the 6th Amendment was concern about protecting the chemical industries' investments in new chemical substances. One way to do this was by protecting certain commercially sensitive information contained in the notifications from disclosure to others than the national competent authorities and the Commission (who must in any event be fully informed).

The question was how to balance the potential conflict between public access to the information in the dossiers and protection of commercially sensitive information.

As with TSCA, these concerns are viewed on the one side as the interests of the general public, workers, and consumers in knowing what information is available about potentially dangerous chemicals and what the bases of governmental responses are, the risks to which they may be exposed and methods of safe handling and disposal, or control of risks. On the other side are the interests of the chemical industries in protecting their investment in developing a new chemical substance, and the interest in society in preserving the vitality and innovative capacity of the chemical industries.

1. Non-confidential information

The Directive begins by defining 5 types of information which may not be held confidential:

- the substance's trade name;

- its physico-chemical properties as defined in Annex VII (3);

- ways of rendering the substance harmless;

.../...

- interpretation of toxicological and ecotoxicological tests and the name of the body responsible for the tests;

- recommended handling methods and precautions, and emergency measures, as defined in Annex VII (2.3, 2.4 and 2.5).

The chemical identity of dangerous substances will appear on the label and may not be kept confidential (Art. 16.2).

Furthermore, the protection of confidentiality is lost if the notifier subsequently releases this information; if the notifier does so it must inform the competent authority (Art. 11 (1)).

2. Commercially sensitive information

The notifier may indicate the information he "considers to be commercially sensitive and disclosure of which might harm him industrially or commercially" and must provide full justification. The competent authority receiving the information decides whether the information shall be treated as confidential, and thus not available to any persons other than the competent authorities and the Commission (Art. 11 (2)).

Information concerning "commercial exploitation or manufacturing" is defined as secret (Art. 7 (3)).

Lastly, the name of a non-dangerous substance may appear on the list of notified substances in encoded form for up to 3 years if publication would give rise to confidentiality problems, at the request of the notifier (Art. 11 (3)).

.../...

3. Structure of protection - safeguards

The Directive states: "confidential information brought to the the attention either of the Commission or of a Member State shall be kept secret" (Art. 11 (4)).

Such information:

- may be brought to the attention only of the authorities whose responsibilities are specified in Article 7 (1);
- may, however, when administrative or legal proceedings involving sanctions are undertaken for the purpose of controlling substances placed on the market, be divulged to persons directly involved in such proceedings (Art. 11 (4)).

The 6th Amendment requires Member States to give stricter protection to confidential information coming from a Member State which has stricter than usual standards (Art. 11 (4)).

A State may refuse to furnish the information if it is not given assurances regarding the observance of these stricter measures.

VI. CLASSIFICATION, LABELLING AND PACKAGING

The EC system for the classification, labelling and packaging of new and existing chemical substances was established in 1967 by the original Directive.

The classification system is designed to identify all of the toxicological, ecotoxicological and physico-chemical properties of substances that are likely to be dangerous in normal handling or use. Classification is based on specified test methods (Annex V), criteria (Annex VI) and 14 definition of "dangerous" - explosive, oxidizing, extremely flammable, highly flammable, flammable, very toxic, harmful, toxic, corrosive, irritant, dangerous for the environment, carcinogenic, teratogenic and mutagenic.

The labelling requirements provide essential information to the general public and to people handling the substance. The label must contain a symbol (Annex II) based on the 9 most important danger categories, standard risk (R) and safety (S) phrases (Annexes III, IV), the name and origin of the substance, and the name and address of the manufacturer, importer or distributor.

The symbols represent the most severe hazards associated with the use of the substance. The R-phrases give a more specific picture of the hazard, and the S-phrases give advice about safety and necessary precautions in handling.

Annex I of the Directive contains a list of about 1,000 substances that are classified and labelled in a uniform manner in the Community. All existing dangerous substances not yet listed in Annex I must be provisionally labelled by

.../...

the manufacturer in accordance with the Directive, in particular with the criteria laid down in Annex VI. This provisional label will remain valid until the substance is listed in Annex I and the EC classification and label is agreed upon, or until the decision is taken not to list the substance in Annex I.

The manufacturer or importer of a new dangerous substance must propose a label to the national authority,in the notification. The proposed label will be reviewed by the Committee for Adaptation to Technical Progress (Art.s 19, 20 and 21) and all new dangerous substances will be included in Annex I.

Thus, the procedure of classification and labelling requires the manufacturers of existing as well as new substances to undertake a preliminary hazard assessment of their chemical substances in order to determine whether and what label would be required.

Annex VI contains the criteria for the toxicological classification of chemical substances. It also contains a detailed Guide for the labelling of new and existing substances, which lays down scientific criteria for classification and labelling, the choice of symbols, risk phrases, and safety phrases.

The Guide was adopted unanimously by the Committee for Adaptation to Technical Progress in summer, 1983. It will soon be adopted as a Commission Directive. The Member States must integrate the Guide into national law by 1 January 1985, and it becomes effective on 1 January 1986.

.../...

VII. IMPLEMENTATION BY THE MEMBER STATES

The core of the 6th Amendment is the system of interdependency among the 10 Member States of the European Community that it has created by establishing a single notification process and empowering each national government to admit new chemical substances into the entire EC market - in effect by acting on behalf of the other 9 Member States.

In terms of concrete requirements, the Member States have very little leeway in implementing the directive. By now, only Luxemburg and Greece have not yet adopted or enacted the necessary regulatory or legislative provisions. These Member States will not be permitted to participate in the exchange of the notifications until they have formally implemented the Directive.

The Commission will enforce the implementation of the Directive vigorously. Divergences from the notification system are not permissible.

PART TWO - DIFFERENCES BETWEEN THE 6TH AMENDMENT AND TSCA

I. OVERVIEW OF STRUCTURAL SIMILARITIES

Before focusing on several of the key differences between the 6th Amendment and TSCA, it seems advisable to review certain essential features that they have in common :

- Both establish the concept of a new chemical substance and the concept of an inventory of "old" substances;
- Both establish a system of notification (as opposed to licensing or permitting) for new commercial chemicals;
- Both require industry to provide government with the basic information necessary to assess the potential hazards and risks of a new chemical substance, and thus to lay a foundation for regulatory action.

The history of these laws shows that these common features did not arise by chance. They clearly derived from the intense discussions about toxic substances policies that have been taking place since the early 1970s at national and international levels of government. The national debates were aided by the active work of many governments in the OECD Chemicals Programme during this period.

It is relevant that the 6th Amendment's notification system forms the basis for proposed chemicals laws in Scandinavia and Austria, and that several OECD Member countries are proposing to incorporate the equivalent Minimum Pre-market Set of Data into their laws.

The discussion below focuses only on certain crucial differences between the two notification systems that seem relevant to understanding their value in the international as well as the national context.

.../...

A more detailed list of specific differences can be found in the table following in Table 3.

It should be kept in mind that TSCA has been in effect for 7 years, and the 6th Amendment for less than 2 years. Therefore not all the aspects and implications of the EC notification system are yet known, and more practical experience has to be gained before all can be identified.

II. KEY DIFFERENCES IN THE NOTIFICATION SYSTEMS

1. Scope

The 6th Amendment differs from TSCA in that the notification is linked to the marketing rather than to the manufacture of new chemical substances.

This reflects the nature of the EC-level of policymaking, which in this case is keyed to the need to protect and enhance the common market by preventing technical barriers to trade. For several reasons, the decision was made to leave the regulation of intermediates to the individual Member States : There were already longstanding and comprehensive national and EC laws on worker protection. Also, the "Post-Seveso" Directive would harmonise and upgrade protection against major accidents where intermediates might escape and affect the environment (5).

Thus, regulation of site-limited intermediates was not thought to have a potentially large enough impact on trade or the environment within the Community to require a Community-wide solution in the light of this existing network of national and EC laws. The decision was not taken on the basis that intermediates did not present any risks to health or the environment or require any further regulation. The Member States are free to regulate chemicals in the workplace more stringently.

Similarly, the exemptions built into the Directive are not based on an assessment of no risk by the Community legislators, but on an assessment that certain less costly controls at the national level would be more appropriate.

.../...

Although manufacturers or importers of exempted substances need not file the full notification with the base set of tests, they must file a limited announcement with each Member State in which the substance is marketed The Member States are free to impose their own requirements for the content of the "announcement" beyond the minimum requirements set by the Directive (Art. 8).

One last general difference in scope lies in the regulatory scheme and possibility for government intervention under the 6th Amendment and TSCA. TSCA sets out a broad system for the regulation of commercial chemicals generally. The 6th Amendment mostly restricts itself to defining a notification scheme for new chemical substances, leaving transitional regulatory controls up to the Member States. Unlike TSCA, it does not provide for control actions during the waiting period before marketing.
It does, however, provide for a procedure to develop a Community-wide control of specific substances.

In fact, the 1976 Directive on the restrictions on the marketing and use of dangerous substances and preparations provides an independent route to regulate chemicals in the European Community (6).

.../...

2. General powers vs specific requirements

The deepest structural difference between TSCA and the 6th Amendment lies in the way they set out the responsibilities of government and industry in their notification schemes. TSCA permits both to exercise great discretion in individual cases by largely defining ultimate responsibilities only. The 6th Amendment would fail in its purpose of achieving a single, common notification system in the 10 Member States if it took this route. It had to lay a firm foundation based on clearly defined, concrete responsibilities to ensure that the burden placed on industries and the powers exercised by the competent authorities in administering the notification system would be fair and equal throughout the Community.

The Community considered the advantages and disadvantages of a system that would permit the manufacturer or importer and the government to decide the most relevant package of information about each new chemical vis-à-vis an administrative system requiring a clear, equal, and financially supportable initial package of information. It adopted the latter approach in the interests of fairness to the affected industries and provided for flexibility where individual circumstances make it necessary. The advantage to governments of having an initial package of equivalent data about new chemicals on the market was also obvious.

The information in the base set is sufficient for an initial risk assessment by the industry, and for government to evaluate the industry's risk assessment. The information is equivalent for all notified chemicals, and thus is the basis for the system of trust in each other's regulatory systems upon which trade in chemicals among the Member States depends.

.../...

The information requirements in the initial notification are consistent with the approach chosen by the 24 OECD Member countries in 1982 and thus integrate the European Community into a wider network of national chemicals control policies. The reciprocal trust that will be generated will rebound to the benefit of the European chemical industries' exports to other countries and to the world's environment and peoples.

The 6th Amendment's choice for precision and clarity does not mean that its notification system lacks flexibility. The opportunity to omit a test in the base set "if it is not technically possible or if it does not appear necessary", the consultative approach towards the imposition of tests at higher levels of marketing, the work of the Committee for Adaptation to Technical Progress, and the meetings of the Commission and competent authorities all guarantee the necessary scientific and administrative flexibility. However, a clearly defined structure of precise obligations and responsibilities remains.

.../..

3. Allocation of responsibilities between industry and government

The 6th Amendment and TSCA appear to have the same approach to allocating responsibilities between government and industry, in that both place the initial burden on industry to develop information about new chemicals and deliver it to government. Upon receipt of the notification, the government first must review it for accuracy and completeness. Then it may respond according to the legal need for action.

In fact, however, as these laws have been implemented it seems that under the 6th Amendment the responsibility of industry to provide adequate information about new chemicals is preserved, while under TSCA most of the responsibility to generate and evaluate information has shifted to government.

4. Information to be supplied with the notification

a) The base set

TSCA and the 6th Amendment differ strikingly in that TSCA does not, per se, require designated testing data to be submitted about each chemical that would be equivalent to the 6th Amendment's notification requirements.

Under the 6th Amendment certain data about a chemical substance must be generated by the industry for notification. Under TSCA such data must only be submitted if they are in the possession or control of the notifier or if they are known or reasonably ascertainable.

TSCA opted for flexibility with the result that government and industry were left in substantial uncertainty about the information that actually would be required in the notification.

.../...

Experience has shown that as a result very little data about the potential health and environmental hazards of new chemicals is submitted at all in the USA.

In contrast, the EC base set places the responsibility to develop an initial, sufficient package of information as well as to evaluate the hazards of a new chemical squarely where the issue arises - with the chemical industry.

The base set in the 6th Amendment is virtually identical to the OECD Minimum-Pre-market Set of Data (MPD). It does not set out disproportionately expensive, in-depth testing for health and environmental hazards. Rather, it sets out a series of commonly recognized tests for specific effects that are generally accepted as indicators of a broad range of hazards. This includes :

Table 1. Annex VII

ANNEX VII

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ('BASE SET') REFERRED TO IN ARTICLE 6 (1)

When giving notification the manufacturer or any other person placing a substance on the market shall provide the information set out below.

If it is not technically possible or if it does not appear necessary to give information, the reasons shall be stated.

Tests must be conducted according to methods recognized and recommended by the competent international bodies where such recommendations exist.

The bodies carrying out the tests shall comply with the principles of good current laboratory practice.

When complete studies and the results obtained are submitted, it shall be stated that the tests were conducted using the substance to be marketed. The composition of the sample shall be indicated.

In addition, the description of the methods used or the reference to standardized or internationally recognized methods shall also be mentioned in the technical dossier, together with the name of the body or bodies responsible for carrying out the studies.

.../...

1. IDENTITY OF THE SUBSTANCE

1.1 Name

1.1.1. Names in the IUPAC nomenclature

1.1.2. Other names (usual name, trade name, abbreviation)

1.1.3. CAS number (if available)

1.2. Empirical and structural formula

1.3 Composition of the substance

1.3.1. Degree of purity (%)

1.3.2. Nature of impurities, including isomers and by-products

1.3.3. Percentage of (significant) main impurities

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ... ppm; ...%

1.3.5. Spectral data (UV, IR, NMR)

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

2. INFORMATION ON THE SUBSTANCE

2.1. Proposed uses

2.1.1. Types of use

Describe: the function of the substance ....
the desired effects ....

2.1.2. Fields or application with approximate breakdown

(a) closed system

- industries ....
- farmers and skilled trades ....
- use by the public at large ....

(b) open system

- industries ....
- farmers and skilled trades ....
- use by the public at large ....

.../...

2.2. **Estimated production and/or imports for each of the anticipated uses or fields of application**

2.2.1. Overall production and/or imports in order of tonnes per year 1; 10; 50; 100; 500; 1 000 and 5 000

— first 12 months .... tonnes/year

— thereafter .... tonnes/year

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2, expressed as a percentage

— first 12 months ....

— thereafter ....

2.3. Recommended methods and precautions concerning:

2.3.1. handling ....

2.3.2. storage ....

2.3.3. transport ....

2.3.4. fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. other dangers, particularly chemical reaction with water

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e.g. poisoning)

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.1. Melting point

.... °C

3.2. Boiling point

.... °C .... Pa

3.3. Relative density

.... (D_4^{20})

3.4. Vapour pressure

.... Pa at .... °C

.... Pa at .... °C

3.5. Surface tension

.... N/m (.............................. °C)

.../...

3.6. Water solubility

.... mg/litre (.............................. °C)

3.7. Fat solubility

Solvent — oil (to be specified)

.... mg/100 g solvent (.............................. °C)

3.8. Partition coefficient

n-octanol/water

3.9. Flash point

.... °C ☐ open cup ☐ closed cup

3.10. Flammability (within the meaning of the definition given in Article 2 (2) (c), (d) and (e))

3.11. Explosive properties (within the meaning of the definition given in Article 2 (2) (a))

3.12. Auto-flammability

.... °C

3.13. Oxidizing properties (within the meaning of the definition given in Article 2 (2) (b))

4. TOXICOLOGICAL STUDIES

4.1. Acute toxicity

4.1.1. Administered orally

LD_{50}.............................. mg/kg

Effects observed, including in the organs ....

4.1.2. Administered by inhalation

LC_{50}.............................. (ppm) Duration of exposure ....hours

Effects observed, including in the organs ....

4.1.3. Administered cutaneously (percutaneous absorption)

LD_{50}.............................. mg/kg

Effects observed, including in the organs ....

4.1.4. Substances other than gases shall be administered via two routes at least, one of which should be the oral route. The other route will depend on the intended use and on the physical properties of the substance.

Gases or volatile liquids should be administered by inhalation (a minimum period of administration of four hours).

In all cases, observation of the animals should be carried out for at least 14 days.

Unless there are contra-indications, the rat is the preferred species for oral and inhalation experiments.

The experiments in 4.1.1, 4.1.2 and 4.1.3 shall be carried out on both male and female subjects.

4.1.5. Skin irritation

The substance should be applied to the shaved skin of an animal, preferably an albino rabbit.

Duration of exposure .... hours

4.1.6. Eye irritation

The rabbit is the preferred animal.

Duration of exposure .... hours

4.1.7. Skin sensitization

To be determined by a recognized method using a guinea-pig.

4.2. Sub-acute toxicity

4.2.1. Sub-acute toxicity (28 days)

Effects observed on the animal and organs according to the concentrations used, including clinical and laboratory investigations ....

Dose for which no toxic effect is observed ....

4.2.2. A period of daily administration (five to seven days per week) for at least four weeks should be chosen. The route of administration should be the most appropriate having regard to the intended use, the acute toxicity and the physical and chemical properties of the substance.

Unless there are contra-indications, the rat is the preferred species for oral and inhalation experiments.

4.3. Other effects

4.3.1. Mutagenicity (including carcinogenic pre-screening test)

4.3.2. The substance should be examined during a series of two tests, one of which should be bacteriological, with and without metabolic activation, and one non-bacteriological.

5. ECOTOXICOLOGICAL STUDIES

5.1. Effects on organisms

5.1.1. Acute toxicity for fish

LC_{50}.............................. (ppm) Duration of exposure determined in accordance with Annex V (C)

Species selected (one or more) ....

5.1.2. Acute toxicity for daphnia

LC_{50}.............................. (ppm) Duration of exposure determined in accordance with Annex V (C)

5.2. Degradation

— biotic

— abiotic

The BOD and the BOD/COD ratio should be determined as a minimum

6. POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS

6.1. For industry/skilled trades

6.1.1. Possibility of recovery ....

6.1.2. Possibility of neutralization ....

6.1.3. Possibility of destruction:

— controlled discharge ....

— incineration ....

.../...

— water purification station ....
— others ....

6.2. **For the public at large**

6.2.1. Possibility of recovery ....

6.2.2. Possibility of neutralization ....

6.2.3. Possibility of destruction:

— controlled discharge ....
— incineration ....
— water purification station ....
— others ....

The 1982 OECD Council Decision on the MPD demonstrates that there is an international consensus that this information is the minimum appropriate to assess a chemical's potential hazards, taking into account all the interests concerned. Interestingly, a similar set of data was defined by a group from American industry and environmental organisations in 1978 (7),

b) Structure - Activity Relationship Analysis (SAR)

The Commission is convinced that structure-activity relationship analysis in no way is an equivalent substitue for test data about the effects of chemical substances. A general principle of toxicology is that small changes in the structure of a chemical may greatly influence the biological activity of the chemical. That is to say, that many biologically active substances differ only slightly in structure but greatly in effects.

.../...

There is no comprehensive, reliable system of predicting the environmental behavior and effects of even simple molecules on the basis of their structure. Only in limited areas (pharmaceuticals, pesticides) have certain correlations been observed - these are the exception, not the rule.

The Commission is supported in its rejection of SAR analysis in favor of test data by statements made at several international meetings (8). The experts participating in the OECD expert groups on existing chemicals share the Commission's scepticism about the current use of SAR as a major tool to evaluate the potential hazards of chemicals.

Regarding the use of SAR analysis in connection with the proposed, precise toxicological criteria for exemptions from the premanufacturing notice proposed by the US EPA, the Commission commented :

"Structure-activity relationship analysis is not safe enough and cannot be used as a single tool when, for instance, very precise definitions of acute toxicity are given, nor can any expert conclude that an untested substance would have these very specific and narrowly defined toxic effects."

Similarly, SAR is incapable of giving a chemical a clean bill of health.

By enacting the 6th Amendment the Governments of the Member States rejected the argument that the base set imposes an inflexible, rigid information burden on the producers of new chemicals.

Likewise, they did not accept that the notification scheme (taking into account the exemptions provided by the Directive) would impose a disproportionate or undue financial burden on the producers of new chemicals.

.../...

5. Follow-up information and further testing

Under the 6th Amendment each manufacturer or importer must provide further information about the new chemical substance at certain levels of market quantities, and under certain circumstances. The type and amount of information is set out by the Directive and to some extent must be negotiated between the competent authority and the notifier.

In contrast, TSCA limits the notification burden solely to the first notifier. Further testing and follow-up information are the subject of several provisions that grant EPA considerable discretion, but subject follow-up reporting requirements to lengthly rulemaking procedures.

It is possible that there is room for convergence between the two systems by taking advantage of the work of the OECD on hazard assessment.

The stepwise testing system chosen by the 6th Amendment should not be considered as merely a screening system that necessarily is followed by more elaborate testing programs. On the contrary, the European Community included in the base set those data which are regarded as indispensable in any case - the higher levels of testing then complement and supplement the base set. This approach is considered necessary in order to evaluate the potential impact on human health and the environment of a chemical by using both qualitative and quantitative criteria as triggers.

The combination of the base set with step-sequence testing and follow-up information requirements offers significant advantages to both governments and industries :

.../...

- It guarantees that a common, minimum set of data will be developed and communicated to government, and that potential hazards will be identified and evaluated by the industry;

- It is combined with a system of exemptions for certain classes of chemicals (polymers, research, test marketing, low volume) to lessen the financial burden placed on innovators in the chemical industries;

- The production quantity triggers alleviate the potential burden on small manufacturers,and notification costs are kept in proportion to volume of trade and potential exposure;

- By establishing clear criteria for further testing, the Directive eliminates one major source of uncertainty about the extent of industry's duty to supply information to the government;

- It also simplifies the work of government;

- It ensures that the financial burden on industry does not become disproportionate to the value of the chemical substance concerned;

- It places the primary responsibility to develop further information on those who have the greatest access to and control of such information - the original notifiers. Hence, in the European Community, the governments are in the position of monitoring and reacting to the information and risk evaluation submitted by the industry. In the USA, on the contrary, the Federal Government appears to carry the primary burden of developing a case for more information and requiring industry to submit it in individual circumstances (9).

PART THREE - IMPLICATIONS FOR INTERNATIONAL TRADE AND THE ENVIRONMENT

International trade in chemicals is lively and growing strongly. Trade in products that contain chemical substances is immeasurably greater.

Once they enter the stream of commerce, it is often difficult or impossible to trace the movement of particular chemicals - they can be transported in products or through the air, soil, and water beyond national frontiers to affect the health and environment of distant nations or even the entire world.

National chemical control policies therefore inevitably have international dimensions; no country can consider itself immune to the decisions of others.

I. TRADE IMPLICATIONS

The European Community and the United States of America are each other's largest trading partner in chemicals as well as products containing chemicals. Hence, any serious differences in the responsibilities placed on manufacturers of chemical substances have obvious international implications as potential barriers to trade.

Of course, whenever some industries are subject to more extensive regulations than others their relative, competitive positions may be affected. But, reliable methods for analyzing the economic impacts of health and environmental regulations have not yet been developed. Consequently, little objective information on the potential impact of the EC notification system on the chemical industries is available. Because the system is quite new, little information has been gathered. For the present, the Commission believes that the intensive and ongoing consultations at all levels of government that went into the development of the 6th Amendment's notification system gave sufficient opportunity to government and the chemical industries to consider the potential trade and financial impacts of the Directive. The adjustments to protect the vitality and innovative capacities of the chemical industries and international trade were made during the political process of drafting the Directive.

Both the European Community and the USA recognized the danger of creating non-tariff trade barriers when TSCA was enacted and have held regular consultations since 1978 to inform each other, and cooperate to avoid potential problems.

.../...

Like TSCA, the 6th Amendment endeavors to put non-domestic suppliers and domestic manufacturers on the same footing in the notification procedure. Where special circumstances apply, the Community, like the EPA, will take account of the need of foreign manufacturers for special treatment in the reporting of confidential business information in the notifications.

At present, the fact is that in the short-term, EC manufacturers and importers to the EC must bear substantially higher costs to develop the information required for notification than in the USA. Since it can be expected that most companies will first market their products domestically, this situation translates into an imbalance between the positions of US and EC chemical industries.

By failing to accept formally the use of the OECD Minimum Pre-Market Set of Data for the notification of new chemicals the EPA has, in effect, put the USA outside the harmonised notification approach of the 24 OECD countries.
Although the EPA recommended that the MPD be used (46 FR 8986, January 27, 1981), this has been ineffective in the light of the USA's subsequent actions to delay and dilute the final OECD Council decision on the MPD, and public statements by the former EPA Administrator of commitment to the alternative approach being practiced under TSCA.

The consequence is that the US chemical industries are granted a short-term financial benefit when they first manufacture chemicals and market them in the USA. Over the longer term, however, the costs to the chemical industries are more equal because US companies marketing in the European Community and the other OECD countries will eventually have to file a notification containing the information in the base set (MPD).

.../...

By choosing such extreme flexibility, the US EPA's implementation of TSCA has made it more difficult for individual companies to know precisely what will be required in a notification. Foreign companies can be expected to have greater difficulty dealing with this vast discretion, indeed, because they are foreign and therefore are less familiar with the US system of government and have less access to regulators in government.

Furthermore, such extreme flexibility leaves the door wide open to individualistic and potentially discriminatory application of the law.

The Commission of the European Communities expressed these concerns to the US EPA on several ocassions during the development of the final PMN rule (10).

.../...

II. HEALTH AND ENVIRONMENTAL IMPLICATIONS

As trade in chemicals and products in worldwide, so, too, are the potential effects of chemicals on people and the environment. The strong trade arguments in favor of harmonising national chemicals policies are supported by even more compelling reasons to develop national policies that will be internationally supportive to protect human health and the environment.

The starting point for any effective policy to protect health and the environment is adequate information about hazards and exposure. This is just what the PMN program under TSCA does not provide.

Because trade in chemicals is only part of the much larger trade in articles containing chemical substances, every country is to some extent dependent on the control policies of its trading partners for protection against dangerous substances. In the 6th Amendment, the European Community ensures that chemical substances marketed within its territory will undergo an equivalent notification procedure that includes toxicological and ecotoxicological tests. If these substances are later exported, other nations will have the assurance of this information gathering and risk assessment by European manufacturers and governments.

It seems probable that ultimately the US Government will be a major beneficiary of the 6th Amendment notification system because the US EPA will be able to receive summaries of the health and safety data by asking for them. If a chemical is first marketed in the Community and later exporte to the USA, it seems probable that the notifer would have to give all the data in the base set to the EPA.

.../...

Other countries lack this assurance when dealing with chemical substances notified under TSCA unless they have been subject to particular EPA action. Thus TSCA provides a loophole through which potentially dangerous substances can enter the world environment without the minimum level of testing agreed upon as appropriate by the OECD.

For chemical substances with potentially global environmental impact, such as chlorofluorcarbons, procedures to regulate substances at the border by regulating imports will be insufficient. The dangerous substances can enter the country by air or water, or in manufactured articles.

Calculations of costs and benefits cannot take into account the real and incalculable benefits to people from a healthy environment. Just as the costs to the chemical industries from the EC notification scheme cannot be precisely determined, neither can the more important benefits to society from a preventive policy such as this be stated simply. Particularly in the case of environmental damage from chemical substances, does the policy of "prevention is better than cure" hold true. Prevention is one of the cornerstones of the European Community's Action Programme on the Environment (1982-1986). In the case of health or environmental injuries which may be irreversible, prevention is the only policy that makes sense, both economically and socially.

.../...

III. INTERNATIONAL HARMONISATION

Both the USA and the European Community have expressed their commitment to the process of international harmonisation of chemicals control policies that has been underway since 1978 - primarily in the OECD. In the past 2 years, the Community has repeatedly stressed the value of this process to representatives of the US Government, despite the USA's apparent efforts to dilute and delay the OECD's work on chemicals.

Of course, harmonisation must proceed in an orderly step-by-step manner, as the work in the OECD has done. There is need to continue this methodical expansion of the areas of scientific and political agreement that provide such a good basis for constructive work together and effective national policies.

The Community bases its strong support for this process of harmonisation on four basic observations dealing with trade, health and environment, resources and administration. Substantial international harmonization has already been accomplished in the OECD Council decisions on the Mutual Acceptance of Data including Good Laboratory Practice and Test Guidelines, the Minimum Pre-marketing Set of Data, and the pending Council recommendations on mutual recognition of compliance with GLP, protection of proprietary rights to data, non-confidential data, and the exchange of confidential data.

First, clearly, these agreements prevent and avoid potential non-tariff barriers to international trade by creating common standards for generating and exchanging information about chemicals.

Second, harmonization can thereby promote better and more consistent protection of health and the environment throughout the world.

Third, it reduces private and public expenditures by strengthening the reliability and the value of the work of laboratories, industries and government.

Fourth, it promotes a stable regulatory environment, which decreases the burden on industry to meet national standards and requirements, and increases the ease of communication and functioning of government, industry and the concerned public.

TABLE 1. EC PREMARKETING NOTIFICATION SCHEME

Moment of notification	At the latest 45 days before marketing
What chemicals must be notified	Those not included in the inventory of chemicals put on the Community market by 18 Sept. 1981 (notified chemicals will not be added to the Inventory)
Who notifies	Any manufacturer or importer (whether first or subsequent) of a notifiable chemical
Where to submit the notification	To the competent authority of the Member State in which the chemical is produced or into which it is imported into the Community
Exemptions	- research and analysis in view of compliance with directive - research and analysis in laboratories for quantities below 1t/year/manufacturer - polymers containing less than 2% of a new monomer - test-marketing (1 year maximum) : brief notification; registered customers - chemicals produced in quantities below 1t/year/manufactuer : brief notification
Content of notification	- technical dossier containing informations, result and description of studies referred to in An. VII - declaration concerning the unfavourable effects in terms of the various uses envisaged - proposed classification and labelling - proposals for any recommended precautions relating to the safe use of the chemical
Further testing and information (Stufenplan)	As provided for in Annex VIII : two additional levels. Triggers : previous results of testing + marketing volume
Follow-up information	- changes in marketing quantities - new knowledge of the effects on man/environment - new uses - changes in properties resulting from the composition of the chemical (impurities, additives, etc.)
Confidentiality	Information to be kept secret from all persons other than the competent authorities and the Commission is decided by the authority owing to proposals by the notifier. Secrecy does not apply to trade name, physico-chemical data, ways of rendering the substance harmless, methods, precautions and emergency measures referred to in Annex VII points 2.3, 2.4, 2.5, interpretation of tox./ecotox. testing.

TABLE 2. INFORMATION SUBMITTAL : STEP - sequence scheme

BASE SET

- Identity of the substance
- Informations on the uses and production
- Physico-chemical properties
- Toxicological studies : acute, subacute toxicity, mutagenicity screening tests
- Ecotoxicological studies : LC 50 for fish and daphnia, degradation
- Possibility of rendering the substance harmless.

1. Q: 10-100 t/y/notifier or 50-500 t cumulated/notifier
2. Results of base set tests

LEVEL 1

- Toxicological studies : fertility study, teratology study, subchronic and/or chronic toxicity study including special studies, additional mutagenesis tests (including screening for carcinogenesis)
- Ecotoxicological studies : algal test, prolonged study with daphnia, prolonged toxicity study with fish, test for species accumulation, prolonged biodegradation study.

1. Q: 1000 t/y/notifier or 5000 t cumulated/notifier
2. Results of base set and level 1 tests.

LEVEL 2

- Toxicological studies : chronic toxicity, carcinogenicity, fertility (3 generations) additional teratology study, acute and subacute toxicity on second species, additional toxicokinetic studies
- Ecotoxicological studies : additional tests for accumulation, degradation and mobility, prolonged toxicity study with fish, birds and other organisms, absorption-desorption study.

TABLE 3. KEY ELEMENTS OF THE TSCA AND 6TH AMENDMENT NOTIFICATION SCHEMES

	TSCA	6th Amendment
1. Moment of notification	Before beginning of manufacture or import	Before marketing
2. Duration of notification period	90 days (+ possibility of 90-day extension)	45 days
3. What chemicals must be notified ?	Chemicals not included in the inventory of 'existing' chemicals ; notified chemicals are added to the inventory.	Chemicals not included in the inventor of chemicals on the Community market at the time where the directive comes into force ; notified chemicals are not added to the inventory
4. Exemptions	- research and development - test-marketing - new chemicals in imported articles - chemicals having no commercial purpose when taken separately (e.g. impurities, by products ....) - certain co-products of limited and defined commercial use (e. g. use as fuel, for landfill or soil-enriching ...)	- research and analysis in view of compliance with directive - research and analysis in laboratorie for quantities below 1 t/year/ manufacturer - polymers containing less than 2% of new monomer - test-marketing (1 year maximum): brief notification - chemicals produced in quantities below 1 t/year/manufacturer: brief notification.
5. Content of dossier	Undefined, but sufficient data must be given to allow risk evaluation	Mandatory base set (annex VII) + 2 additional steps (anne VIII); triggers = previous results + quantite

ANNEX I

October 1982

AIDE MEMOIRE

Subject: Comments of the European Community on "Premanufacture Notification: Proposed Exemption for Site-Limited Intermediate Chemical Substances and Chemical Substances Manufactured in Quantities of 10,000 Kg or less per year" (47 FR 33896-33923) and on "Premanufacture Notification: Proposed Exemption for Polymers" (47 FR 33924-33948).

1. On 4 August 1982, the United States Environmental Protection Agency (EPA) published two proposed rules under section 5(h)(4) of the Toxic Substances Control Act (TSCA), granting general exemptions from notification to manufacturers of site-limited intermediates, low volume chemicals, and certain polymers.

   The European Community has carefully studied the U.S. proposals and would like to submit the following initial comments.

2. Since 1978, the United States and the European Community have initiated and supported international efforts within the Organisation for Economic Development and Cooperation (OECD) and negotiated bilaterally to harmonize national toxic substances control laws, for the dual purpose of developing convergent environmental policies and eliminating non-tariff barriers to trade. The European Community understands that EPA has designed these proposed exemption rules to fit the requirements of the Toxic Substances Control Act, namely the balancing between risk and benefit contained in the definition of "unreasonable risk." Nevertheless, as a first general comment, the European Community regrets that EPA has not chosen this opportunity even to attempt to harmonize some of the TSCA regulations with the '6th Amendment to the 1967 Directive on dangerous substances' (Directive 79/831/EEC).

It is true, that at first glance the exemption rules now proposed by EPA give the impression of being consistent with the goal of harmonization. However, a closer examination of the exemption proposals discloses that in fact there are significant and serious divergences.

The exemptions under the 6th Amendment cannot be compared with the proposed exemptions under TSCA without taking into account the overall framework established by each law.

The 6th Amendment combines its exemptions with a strict, heirarchical system of testing and follow-up information based on levels of marketing that has no parallel in TSCA.

3. The proposed U.S. exemptions differ from the exemptions provided in article 8 of the 6th Amendment of the 1967 directive on dangerous substances (Directive 79/831/EEC) both in scope and in procedures. One major difference resides in the fact that the categories of exempted substances are defined differently under TSCA and the 6th Amendment.

Furthermore, the complicated and subjective nature of the proposed exemptions under TSCA will put European companies at a double disadvantage.

European manufacturers, who are accustomed to the unambiguous exemptions under the 6th Amendment, will have difficulty comprehending the complexities of the U.S. proposals.
The exemptions are subject to revocation by EPA, which may lead to discrimination against European manufacturers.

4. The European Community wishes to stress to EPA that the exemption rules should not weaken the control of chemicals in the United States. It is clear that many provisions of TSCA are based on the very high involvement of EPA, which is the basis of the good functioning of the U.S. toxic substances control programme. If EPA reduces its role in the implementation of TSCA, then the information provided by industry should be increased to maintain a comparable level of toxic sustances control.

The U.S. chemical industry repeatedly has complained that it was placed in a disadvantageous position compared to its EC counterpart, because at least half the substances which had to be notified in the United States do not have to be notified in the EC.

The European Community does not think that this reasoning is justifiable, since on the other hand, the European industry must face high testing requirements under the 6th Amendment.

Because the number of notifiable new substances in the USA could decrease by as much as 80% under the proposed regulations, the European Community sees no reason for furhter delay in application of the OECD Minimum Premarketing Set of Data to substances which would still be subject to premanufacture notification in the United States.

5. It is obvious that industry will not carry out more tests for an exemption notice than for a full premanufacture notification. Therefore, how does one determine wheter a chemical is eligible for exemptions? Structure-activity relationship analysis is not safe enough and cannot be used as single tool when, for instance, very precise definitions of acute toxicity are given, nor can any expert conclude that an untested substance would have these very specific and narrowly defined toxic effects.

Where the definitions refer to specific tests, the principles applied should be in accordance with the OECD Test Guidelines and Principles of Good Laboratory Practice, adopted by the OECD Council on 12 May 1981.

6. EPA request comments on the adequacy of the proposed standards for exclusion from the exemptions (acute toxicity specific chronic effects). It is the opinion of the European Community, that it is here less a case of adequacy of standards than of implementation and respect of these standards.

   In the absence of testing results or systematic control by EPA, there will be no guarantee of adequate implementation of these standards, despite the review by and industry--employed qualified expert. According to the proposed rules it appears that industry will be in a position to authorize its own exemptions, although in theory EPA will have 14 days to intervene. However, the 14-day period can not be sufficient for in-depht review of the exemption notices, since the expert'es analysis will not be submitted to EPA with the exemption notice.

7. Especially condidering the lack of testing data characteristic of the present notification procedure, the European Community is of the opinion that the difference between a 14-day review period and the full 90-day PMN period is too large.

   Companies could regularly file exemption notices hoping to get past the 14-day review period and to begin manufacture earlier than with a full Pre-manufacture Notification (PMN). Then, even if a full PMN had to be filed at a later state, the manufacturer would already have establidhed a share of the market. The preventive nature of TSCA would be undermined, because EPA would be in a much more difficult position to initiate control actions under sections 5(e) or 5(f) of TSCA, which are indispensable complements to the U.S. notification process.

8. Finally, the European Community fears that the proposed exemption rules for low volume chemicals would in practice create non-tariff barriers to trade. Indeed, as these exemptions are restricted to the first manufacturer and submitted to EPA, there is every change that the system will favour U.S. firms, since they are in a better position to deal with EPA and have a better knowledge of U.S. regulations than Community-based firms.

   Probably, this will lead to sole use of the exemptions by U.S. firms, although this is not directly obvious from the text.

9. EPA has asked for comments on an equitable solution to the problem of limiting the low volume exemtpions tot he first manufacturer or importer.

   In the view of the European Community, this should be achieved by dropping the 10,000 Kg limit and allowing exemptions to the first and subsequent manufacturers reporting 1,000 Kg or less.

   This would have the advantage of:

   - removing the inequity from the proposed system, which threatens to penalize importers and

   - bringing the U.S. regulations closer to those existing in the European Community.

   The Environmental Protection Agency then would be able to monitor more easily the number of exemptions.

10. In conclusion, the European Community hopes that the Environmental Protection Agency, in balancing risks to human health and the environment against economic benefits, will not give excessive weightto the latter.

COUNCIL DIRECTIVE

of 18 September 1979

amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(79/831/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas to protect man and the environment against potential risks which could arise from the placing on the market of new substances, it is necessary to lay down appropriate measures and in particular to reinforce the recommendations provided in Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (3), as last amended by Directive 75/409/EEC (4);

Whereas it is necessary for these reasons to amend Directive 67/548/EEC which at the moment by an adequate classification, packaging and labelling of dangerous substances protects the population and principally the workers using them;

Whereas in order to control the effects on man and the environment it is advisable that any new substance placed on the market be subjected to a prior study by the manufacturer or importer and a notification to the competent authorities conveying mandatorily certain information; whereas it is, moreover, important to follow closely the evolution and use of new substances placed on the market, and that in order to do this it is necessary to institute a system which allows all new substances to be listed;

Whereas, moreover, it is necessary, if the Directive is to be properly applied, to draw up an inventory of substances on the Community market by 18 September 1981;

Whereas it is necessary to provide for measures making it possible to introduce a procedure of notification to one Member State which is then valid for the Community; whereas, it is, moreover, necessary to provide that the measures relating to the classification and labelling of substances may be laid down at Community level;

Whereas it is necessary to introduce measures for the packaging and provisional labelling of dangerous substances not yet appearing in Annex I to Directive 67/548/EEC;

Whereas it is necessary to make the indication of safety advice obligatory;

Whereas Article 2 of the abovementioned Directive classifies substances and preparations as toxic, harmful, corrosive or irritant by the use of general definitions; whereas experience has shown that it is necessary to improve this classification; whereas in the absence, at the moment, of specifications necessary for allocation to these classes, it seems appropriate to provide precise criteria for classification; whereas in addition Article 3 of the Directive provides for an evaluation of danger for the environment and it is therefore necessary to enumerate certain characteristics and parameters of assessment, and to establish a phased study programme,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Articles 1 to 8 of Directive 67/548/EEC are hereby replaced by the following Articles:

'*Article 1*

1. The purpose of this Directive is to approximate the laws, regulations and administrative provisions of the Member States on:

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(1) OJ No C 30, 7. 2. 1977, p. 35.

(2) OJ No C 114, 11. 5. 1977, p. 20.

(3) OJ No 196, 16. 8. 1967, p. 1.

(4) OJ No L 183, 14. 7. 1975, p. 22.

(a) the notification of substances, and

(b) the classification, packaging and labelling of substances dangerous to man and the environment,

which are placed on the market in the Member States.

2. This Directive does not apply to the provisions relating to:

(a) medicinal products, narcotics and radioactive substances;

(b) the carriage of dangerous substances by rail, road, inland waterway, sea or air;

(c) foodstuffs or feedingstuffs;

(d) substances in the form of waste which are covered by Council Directive 75/442/EEC of 15 July 1975 relating to waste (¹) and Council Directive 78/319/EEC of 20 March 1978 relating to toxic and dangerous waste (²);

(e) substances in transit which are under customs supervision provided they do not undergo any treatment or processing.

3. Articles 15, 16 and 17 do not apply to the provisions governing:

(a) containers which contain gases compressed, liquefied or dissolved under pressure, excluding aerosols which comply with the requirements of Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (³);

(b) munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect.

4. Articles 5, 6 and 7, in so far as they are concerned with notification, do not apply:

(a) — until six months after publication of the inventory referred to in Article 13 (1), to substances placed on the market before 18 September 1981;

— six months after publication of the inventory referred to in Article 13 (1), to substances which appear in that inventory;

(b) to pesticides and fertilizers, in as far as they are subject to approval procedures which are at least equivalent or Community notification procedures or procedures which are not yet harmonized;

(c) to substances which are already subject to similar testing and notification requirements under existing Directives.

Article 2

1. For the purpose of this Directive:

(a) "substances" means chemical elements and their compounds as they occur in the natural state or as produced by industry, including any additives required for the purpose of placing them on the market;

(b) "preparations" means mixtures or solutions composed of two or more substances;

(c) "environment" means water, air and land and their inter-relationship as well as relationships between them and any living organisms;

(d) "notification" means the documents whereby the manufacturer or any other person established in the Community who places a substance on its own or in a preparation on the market presents the requisite information to the competent authority of a Member State. The person so doing shall hereinafter be referred to as "the notifier";

(e) "placing on the market" means supplying or making available to third parties.

Importation into Community customs territory shall be deemed to be placing on the market for the purposes of this Directive.

2. The following substances and preparations are "dangerous" within the meaning of this Directive:

(a) explosive:

substances and preparations which may explode under the effect of flame or which are more sensitive to shocks or friction than dinitrobenzene;

(b) oxidizing:

substances and preparations which give rise to highly exothermic reaction when in contact with other substances, particularly flammable substances;

(c) extremely flammable:

liquid substances and preparations having a flash point lower than 0 °C and a boiling point lower than or equal to 35 °C;

(¹) OJ No L 194, 15. 7. 1975, p. 39.
(²) OJ No L 84, 31. 3. 1978, p. 43.
(³) OJ No L 147, 9. 6. 1975, p. 40.

(d) highly flammable:

- substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or
- solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or
- liquid substances and preparations having a flash point below 21 °C, or
- gaseous substances and preparations which are flammable in air at normal pressure, or
- substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

(e) flammable:

liquid substances and preparations having a flash point equal to or greater than 21 °C and less than or equal to 55 °C;

(f) very toxic:

substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve extremely serious, acute or chronic health risks and even death;

(g) toxic:

substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve serious, acute or chronic health risks and even death;

(h) harmful:

substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve limited health risks;

(i) corrosive:

substances and preparations which may, on contact with living tissues, destroy them;

(j) irritant:

non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, can cause inflammation;

(k) dangerous for the environment:

substances and preparations the use of which presents or may present immediate or delayed risks for the environment;

(l) carcinogenic:

substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer in man or increase its incidence;

(m) teratogenic;

(n) mutagenic.

Article 3

1. The physico-chemical properties of the substances and preparations shall be determined according to the methods specified in Annex V (A); their toxicity shall be determined according to the methods specified in Annex V (B) and their ecotoxicity according to those specified in Annex V (C).

2. The real or potential environmental hazard shall be assessed according to the characteristics set out in Annexes VII and VIII, on the basis of any existing internationally recognized parameters.

3. The general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI, save where contrary requirements for dangerous preparations are specified in separate Directives.

Article 4

1. The classification of dangerous substances according to the degree of hazard and to the specific nature of the risks involved shall be based on the categories laid down in Article 2 (2). For categories (a) to (j) the substances shall be classified according to the greatest degree of hazard, in accordance with Article 16 (4).

2. The dangerous substances listed in Annex I shall, where appropriate, be given a rating enabling the health hazard of preparations to be assessed. The ratings shall be determined in accordance with the criteria established by a subsequent Council Directive.

Article 5

1. The Member Sates shall take all the measures necessary to ensure that without prejudice to Article 8 substances cannot be placed on the market on their own or in preparations unless the substances have been:

- notified to the competent authority of one of the Member States in accordance with this Directive,
- packaged and labelled in accordance with Articles 15 to 18 and with the criteria in Annex VI, and in accordance with the results of the tests provided for in Article 6.

2. The measures referred to in the second indent of paragraph 1 shall apply until the substance is listed in Annex I or until a decision not to list it has been taken in accordance with the procedure laid down in Article 21.

Dangerous substances not yet appearing in Annex I but included in the list referred to in Article 13 (1) or already on the market before 18 September 1981 must, in so far as the manufacturer whether or not established in the Community may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 15 to 18 and with the criteria in Annex VI.

Article 6

1. Without prejudice to Articles 1 (4) and 8 (1), any manufacturer or importer into the Community of a substance within the meaning of this Directive shall be required to submit to the competent authority referred to in Article 7 of the Member State in which the substance is produced or into which it is imported into the Community, at the latest 45 days before the substance is placed on the market, a notification including:

— a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing at least the information and results of the studies referred to in Annex VII, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them,

— a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged,

— the proposed classification and labelling of the substance in accordance with this Directive,

— proposals for any recommended precautions relating to the safe use of the substance.

2. However, in the case of a substance which has already been notified, the competent authority may agree that the notifier of that substance may, for the purposes of the technical dossier, refer to the results of the studies carried out by one or more previous notifiers, provided the latter have given their agreement in writing.

3. If a substance is already listed in Annex I, the notifier need not present the declaration concerning its unfavourable effects, the proposed classification and the proposals for any recommended precautions relating to safe use. Furthermore, the notifier need not supply the information required for the technical dossier in Annex VII, with the exception of points 1 and 2 of that Annex, if the substance was originally notified at least 10 years previously.

4. Any notifier of a substance already notified shall be required to inform the competent authority of:

— changes in the annual or total quantities placed on the market by him in accordance with the tonnage range laid down in Annex VII, point 2.2.1,

— new knowledge of the effects of the substance on man and/or the environment of which he may reasonably be expected to have become aware,

— new uses for which the substance is placed on the market (within the meaning of Annex VII, point 2.1.2) of which he may reasonably be expected to have become aware,

— any change in the properties resulting from a modification of the substance referred to in Annex VII, point 1.3.

5. The notifier shall also be required to inform the competent authority of the results of the studies carried out in accordance with Annex VIII.

Article 7

1. Member States shall appoint the competent authority or authorities responsible for receiving the information provided for in Article 6 and examining its conformity with the requirements of the Directive, and in particular:

— the notifier's proposed findings on any foreseeable risks which the substance may entail,

— classification and labelling,

— the proposals for any recommended precautions relating to safe use submitted by the notifier.

Moreover, if it can be shown to be necessary for the evaluation of the hazard which may be caused by a substance, the competent authorities may:

— ask for further information and/or verification tests concerning the substances of which they have been notified; this may also include requesting the information referred to in Annex VIII earlier than provided for therein,

— carry out such sampling as is necessary for control purposes,

— take appropriate measures relating to safe use of a substance pending the introduction of Community provisions.

2. The procedure laid down in Article 21 shall be followed in confirming or amending proposals for:

- — classification,
- — labelling, and
- — the recommended precautionary measures provided for in Annex VII, points 2.3, 2.4 and 2.5.

3. Member States and the Commission shall ensure that any information concerning commercial exploitation or manufacturing is kept secret.

Article 8

1. The substances listed below, shall be considered as having been notified within the meaning of this Directive when the following conditions are fulfilled:

- — polymerizates, polycondensates and polyadducts except those containing in combined form 2% or more of any monomer unmarketed before 18 September 1981,
- — substances for research and analysis purposes, in so far as they are placed on the market for the purpose of determining their properties in accordance with this Directive;
- — substances placed on the market for research or analysis purposes in quantities of less than one tonne per year per manufacturer or importer and intended solely for laboratories,
- — substances placed on the market in quantities of less than one tonne per year per manufacturer provided that the manufacturer announces their identity, labelling data and quantity to the competent authorities of the Member States where the substances are placed on the market and complies with any conditions imposed by those authorities.

However, substances placed on the market at the research and development stage with a limited number of registered customers, in quantities which are limited to the purpose of the research and development but which amount to more than one tonne per year per manufacturer, shall qualify for exemption for a period of one year, provided that the manufacturer announces their identity, labelling data and quantity to the competent authorities of each Member State where the manufacture, research or development takes place and complies with any conditions imposed by those authorities on such research and development; after this period, these substances shall be subject to notification. The manufacturer shall also give an assurance that the substance or the preparation in which it is incorporated will be handled by customers' staff only, under controlled conditions, and will not be made available to the public.

2. The substances referred to in paragraph 1 must, in so far as the manufacturer may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 15 to 18 and with the criteria imposed in Annex VI.

If labelling in accordance with the principles set out in Article 16 is not yet possible, the label should bear the warning: "Caution — substance not yet fully tested".

3. Where a substance as referred to in paragraph 1, labelled in accordance with the principles set out in Article 16, is very toxic or toxic, the manufacturer or importer of such a substance must transmit to the competent authority any appropriate information as regards Annex VII, points 2.3, 2.4 and 2.5.

Article 9

When a Member State has received the notification dossier or additional information referred to in Article 6 it shall forthwith send to the Commission a copy of the dossier or a summary thereof together with any relevant comments; in the case of the further information referred to in Article 7 (1) and the additional information or studies provided for in Annex VIII, the competent authority shall notify the Commission of the tests chosen, the reasons for their choice, and the assessment of their results.

Article 10

1. On receipt of the copy of the notification dossier, the summary thereof or the additional information sent by a Member State, the Commission shall forward:

- — the notification dossier or the summary thereof to the other Member States,
- — any other relevant information it has collected pursuant to this Directive to all Member States.

2. The competent authority of any Member State may consult direct the competent authority which received the original notification, or the Commission, on specific details of the data

contained in the dossier required under this Directive; it may also suggest that further tests or information be requested. If the competent authority which received the original notification fails to comply with the suggestions of other authorities regarding further information or amendments in the study programmes provided for in Annex VIII, it shall give its reasons to the other authorities concerned. Should it not be possible for the authorities concerned to reach agreement and should any one authority feel, on the basis of detailed reasons, that additional information or amendments in the study programmes are nevertheless really necessary to protect man and the environment, it may ask the Commission to take a decision in accordance with the procedure laid down in Article 21.

Article 11

1. If he considers that there is a confidentiality problem, the notifier may indicate the information provided for in Article 6 which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than the competent authorities and the Commission. Full justification must be given in such cases.

Industrial and commercial secrecy shall not apply to:

— the trade name of the substance,

— physico-chemical data concerning the substance in connection with Annex VII, point 3,

— the possible ways of rendering the substance harmless,

— the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests,

— the recommended methods and precautions referred to in Annex VII, point 2.3 and the emergency measures referred to in Annex VII, points 2.4 and 2.5.

If the notifier himself subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.

2. The authority receiving the notification shall decide on its own responsibility which information is covered by industrial and commercial secrecy in accordance with paragraph 1.

3. The name of a substance appearing in the list provided for in Article 13 (2) may be included in encoded form where the competent authority to which the notification has been submitted so requests because of the confidentiality problems to which publication of the name of the substance would give rise, provided that the substance is not classified as dangerous.

A substance may be included in the list in encoded form for no longer than three years.

4. Confidential information brought to the attention either of the Commission or of a Member State shall be kept secret.

In all cases such information

— may be brought to the attention only of the authorities whose responsibilities are specified in Article 7 (1),

— may, however, when administrative or legal proceedings involving sanctions are undertaken for the purpose of controlling substances placed on the market, be divulged to persons directly involved in such proceedings.

This Article and Article 12 shall not oblige a Member State whose legislation or administrative practices impose stricter limits for the protection of industrial and commercial secrecy than those laid down in these Articles to supply information, where the State concerned does not take steps to comply with these stricter limits.

Article 12

The data supplied in accordance with Articles 9 and 10 (1) may be forwarded to the Commission and the Member States in summary form.

In such cases and in the context of Article 10 (2), the competent authorities of a Member State and the Commission shall have access to the notification dossier and the additional information at all times.

Article 13

1. The Commission shall, on the basis in particular of information provided by the Member States, draw up an inventory of substances on the Community market by 18 September 1981.

In so doing it shall have regard to Articles 1 (4) and 8.

The inventory shall give the chemical name under an internationally recognized chemical nomenclature (preferably IUPAC), the CAS number and the common name or ISO abbreviation, if any.

2. The Commission shall keep a list of all substances notified under this Directive.

3. The information and the form in which it is recorded in the list and the inventory, together with the criteria covering the provision to the Commission by the Member States of information relating to the inventory, shall be determined in accordance with the procedure laid down in Article 21.

Article 14

Annex I contains the list of substances classified in accordance with Article 4 and any recommendations relating to safe use.

Article 15

1. Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless their packaging satisfies the following requirements:

(a) it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed;

(b) the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form harmful or dangerous compounds with the contents;

(c) packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;

(d) containers fitted with replaceable fastening devices shall be so designed that the packaging can be repeatedly refastened without the contents escaping.

2. The Member States may also prescribe that:

— packages shall initially be closed with a seal in such a way that when the package is opened for the first time the seal is irreparably damaged,

— containers with a capacity not exceeding three litres which contain dangerous substances intended for domestic use shall have child-resistant fastenings,

— containers with a capacity not exceeding one litre which contain very toxic, toxic or corrosive liquids intended for domestic use shall carry a tactile warning of danger.

3. Any technical specifications which may be necessary with regard to the devices referred to in paragraph 2 shall be adopted by the procedure in Article 21 and shall be given in Annex IX, in particular:

— in Annex IX (A) relating to child-resistant fastenings,

— in Annex IX (B) relating to tactile warnings of danger.

Article 16

1. Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless the labelling on their packaging satisfies the following requirements.

2. Every package shall show clearly and indelibly the following:

— the name of the substance,

— the origin of the substance,

— the danger symbol, when laid down, and indication of danger involved in the use of the substance,

— standard phrases indicating the special risks arising from such dangers,

— standard phrases indicating the safety advice relating to the use of the substance.

(a) The name of the substance shall be one of the terms listed in Annex I; if this is not the case the name must be given in accordance with internationally recognized nomenclature.

(b) The indication of origin shall include the name and address of the manufacturer, the distributor or the importer.

(c) The following symbols and indications of danger are to be used:

— explosive:
an exploding bomb (E)

— oxidizing:
a flame over a circle (O)

— extremely flammable:
a flame (F)

— highly flammable:
a flame (F)

- very toxic:
  a skull and cross-bones (T)
- toxic:
  a skull and cross-bones (T)
- harmful:
  a St Andrew's cross (Xn)
- corrosive:
  the symbol showing the damaging effect of an acid (C)
- irritant:
  a St Andrew's cross (Xi)

The symbols must conform to those in Annex II; they shall be printed in black on an orange-yellow background.

(d) The special risks involved in using the substances shall be indicated by one or more of the standard phrases which, in accordance with the references contained in the list in Annex I, are set out in Annex III. In the case of a substance not listed in Annex I, the reference to the special risks attributed to the dangerous substances shall comply with appropriate indications given in Annex III.

The phrases "extremely flammable" or "highly flammable" need not be indicated where they repeat the wording of an indication of danger used in accordance with (c) above.

(e) The safety advice relating to the use of the substances shall be indicated by standard phrases which, in accordance with the references contained in the list in Annex I, are set out in Annex IV.

The packaging shall be accompanied by the safety advice required by the above paragraph where it is materially impossible for this to be given on the label or package itself.

In the case of a substance not listed in Annex I, the safety advice relating to the dangerous substances shall comply with appropriate indications given in Annex IV.

(f) Indications such as "non-toxic", "non-harmful" or any other similar indications must not appear on the label or packaging of substances subject to this Directive.

3. In the case of irritant, highly flammable, flammable and oxidizing substances, an indication of special risks and safety advice need not be given where the package does not contain more than 125 ml. This shall also apply in the case of the same volume of harmful substances not retailed to the general public.

4. When more than one danger symbol is assigned to a substance:

- the obligation to indicate the symbol T makes the symbols X and C optional, unless Annex I includes provision to the contrary,
- the obligation to indicate the symbol C makes the symbol X optional,
- the obligation to indicate the symbol E makes the symbols F and O optional.

Article 17

1. Where the particulars required by Article 16 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that these particulars can be read horizontally when the package is set down normally. The dimensions of the label shall be as follows:

Capacity of the package	*Dimensions (in millimetres)*
— not exceeding three litres:	if possible at least 52 × 74
— greater than three litres but not exceeding 50 litres:	at least 74 × 105
— greater than 50 litres but not exceeding 500 litres:	at least 105 × 148
— greater than 500 litres:	at least 148 × 210

Each symbol shall cover at least one tenth of the surface area of the label but not be less than 1 cm². The entire surface of the label shall adhere to the package immediately containing the substance.

These dimensions are intended solely for provision of the information required by this Directive and if necessary of any supplementary health or safety indications.

2. A label is not required where the particulars are clearly shown on the package itself, as specified in paragraph 1.

3. The colour and presentation of the label — or, in the case of paragraph 2, of the package — shall be such that the danger symbol and its background stand out clearly from it.

4. Member States may make the placing on the market of dangerous substances in their territories subject to the use of the official language or languages in respect of the labelling thereof.

5. For the purpose of this Directive, labelling requirements shall be deemed to be satisfied:

(a) in the case of an outer package containing one or more inner packages, if the outer package is labelled in accordance with international rules on the transport of dangerous substances and the inner package or packages are labelled in accordance with this Directive;

(b) in the case of a single package, if such a package is labelled in accordance with international rules on the transport of dangerous substances and with Article 16 (2) (a), (b), (d) and (e).

Where dangerous substances do not leave the territory of a Member State, labelling may be permitted which complies with national rules instead of with international rules on the transport of dangerous substances.

Article 18

1. Member States may:

(a) permit the labelling required by Article 16 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 17 (1) and (2);

(b) by way of derogation from Articles 16 and 17 permit the packaging of dangerous substances which are neither explosive, very toxic nor toxic to be unlabelled or to be labelled in some other way if they contain such small quantities that there is no reason to fear any danger to persons handling such substances or other persons.

2. If a Member State makes use of the options provided for in paragraph 1, it shall forthwith inform the Commission thereof.

Article 19

The amendments necessary for adapting the Annexes, other than Annex VI, Part I and Annexes VII and VIII, to technical progress, shall be adopted in accordance with the procedure laid down in Article 21.

Article 20

1. A Committee (hereinafter called "the Committee") is hereby set up to adapt to technical progress the Directives concerning the elimination of technical barriers to trade in dangerous substances and preparations. It shall consist of representatives of the Member States, with a Commission representative as chairman.

2. The Committee shall adopt its own rules of procedure.

Article 21

1. Where reference is made to the procedure laid down in this Article, the matter shall be referred to the Committee by its chairman, either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit a draft of the measures to be adopted to the Committee. The Committee shall give its view on the draft within a time limit set by the chairman having regard to the urgency of the matter. Decisions shall be taken by a majority of 41 votes, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the proposed measures if they are in accordance with the opinion of the Committee;

(b) If the proposed measures are not in accordance with the opinion of the Committee, or if no opinion has been stated, the Commission shall without delay submit a proposal to the Council concerning the measures to be adopted. The Council shall act by a qualified majority;

(c) If the Council has not acted within three months of the proposal being submitted to it, the proposed measures shall be adopted by the Commission.

Article 22

The Member States may not, on grounds relating to notification, classification, packaging or labelling within the meaning of this Directive, prohibit, restrict or impede the placing on the market of substances which comply with the requirements of this Directive and the Annexes thereto.

Article 23

1. Where a Member State has detailed evidence that a substance, although satisfying the requirements of this Directive, constitutes a hazard for man or the environment by reason of its classification packaging or labelling, it may provisionally prohibit the sale of that substance or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. The Commission shall consult the Member States concerned within six weeks, then give its view without delay and take the appropriate measures.

3. If the Commission considers that technical adaptations to this Directive are necessary, such adaptations shall be adopted, either by the Commission or by the Council, in accordance with the procedure laid down in Article 21; in such case, the Member State which has adopted safeguard measures may maintain them until the adaptations enter into force.'

Article 2

Articles 9, 10 and 11 of Directive 67/548/EEC hereby become Articles 24, 25 and 26.

Article 3

Annex V to Directive 67/548/EEC is hereby replaced by Annexes V to IX to this Directive.

Article 4

The following amendments shall be made to the Directives listed below:

(a) Directive 73/173/EEC:

- replace 'Article 6' by 'Article 16' in Article 5 (2) (c),
- replace 'Article 8c' by 'Article 21' in Articles 9 (2) and 10;

(b) Directive 77/728/EEC:

- replace 'Article 6' by 'Article 16' in Article 6 (2) (c),
- replace 'Article 8c' by 'Article 21' in Articles 10 (3) and 11;

(c) Directive 78/631/EEC:

- replace 'Article 6' by 'Article 16' in Article 6 (2) (g),
- replace 'Article 8c' by 'Article 21' in Articles 10 (3) and 11.

Article 5

1. No later than 18 September 1981 the Member States shall implement the laws, regulations and administrative provisions necessary to comply with Articles 1 to 4, Article 5 (1) and Articles 6 to 14 of Directive 67/548/EEC as amended by this Directive and shall inform the Commission thereof. No later than 18 September 1983 they shall implement the laws, regulations and administrative provisions necessary to comply with Article 5 (2) of Directive 67/548/EEC as amended by this Directive and shall inform the Commission thereof.

2. No later than 18 September 1981 the Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with Articles 15 to 23 of Directive 67/548/EEC as amended by this Directive, which shall enter into force on 18 September 1981.

3. During the transitional period, when this Directive is not yet in force in certain Member States, the forwarding of the notification dossier and any other information collected by the Commission as provided for in Article 10 (1) of Directive 67/548/EEC as amended by this Directive shall be effective in the case of only those Member States in which the provisions of Articles 5 to 8 of Directive 67/548/EEC as amended by this Directive, relating to notification, are being applied.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 18 September 1979.

For the Council

The President

M. O'KENNEDY

ANNEX V

A. **METHODS FOR THE DETERMINATION OF PHYSICO-CHEMICAL PROPERTIES:** for the record

B. **METHODS FOR THE DETERMINATION OF TOXICITY:** for the record

C. **METHODS FOR THE DETERMINATION OF ECOTOXICITY:** for the record

ANNEX VI

GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES

Part I

A. Save where otherwise provided in the separate Directives on dangerous preparations, the substances and preparations shall be classified as very toxic, toxic or harmful according to the following criteria:

(a) classification as very toxic, toxic or harmful shall be effected by determining the acute toxicity of the commercial substance or preparation in animals, expressed in LD_{50} or LC_{50} values with the following parameters being taken as reference values:

Category	LD_{50} absorbed orally in rat mg/kg	LD_{50} percutaneous absorption in rat or rabbit mg/kg	LC_{50} absorbed by inhalation in rat mg/litre/four hours
Very toxic	≤ 25	≤ 50	≤ 0·5
Toxic	25 to 200	50 to 400	0·5 to 2
Harmful	200 to 2 000	400 to 2 000	2 to 20

(b) if facts show that for the purposes of classification it is inadvisable to use the LD_{50} or LC_{50} values as a principal basis because the substances or preparations produce other effects, the substances or preparations shall be classified according to the magnitude of these effects.

Part II

B. — Corrosion criteria: for the record
— Irritation criteria: for the record

C. If the facts show the existence of effects other than the acute effects indicated by experiments with animals, e.g. carcinogenic, mutagenic, allergenic, sub-acute or chronic effects, the substances or preparations shall be classified according to the magnitude of these effects.

D. Guide for the labelling of dangerous substances and criteria for the choice of phrases allocated to dangerous substances indicating the special risks (R phrases) and the safety advice (S phrases): for the record.

ANNEX VII

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ('BASE SET') REFERRED TO IN ARTICLE 6 (1)

When giving notification the manufacturer or any other person placing a substance on the market shall provide the information set out below.

If it is not technically possible or if it does not appear necessary to give information, the reasons shall be stated.

Tests must be conducted according to methods recognized and recommended by the competent international bodies where such recommendations exist.

The bodies carrying out the tests shall comply with the principles of good current laboratory practice.

When complete studies and the results obtained are submitted, it shall be stated that the tests were conducted using the substance to be marketed. The composition of the sample shall be indicated.

In addition, the description of the methods used or the reference to standardized or internationally recognized methods shall also be mentioned in the technical dossier, together with the name of the body or bodies responsible for carrying out the studies.

1. IDENTITY OF THE SUBSTANCE

1.1 Name

1.1.1. Names in the IUPAC nomenclature

1.1.2. Other names (usual name, trade name, abbreviation)

1.1.3. CAS number (if available)

1.2. Empirical and structural formula

1.3 Composition of the substance

1.3.1. Degree of purity (%)

1.3.2. Nature of impurities, including isomers and by-products

1.3.3. Percentage of (significant) main impurities

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ... ppm; ... %

1.3.5. Spectral data (UV, IR, NMR)

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

2. INFORMATION ON THE SUBSTANCE

2.1. Proposed uses

2.1.1. Types of use

Describe: the function of the substance ....

the desired effects ....

2.1.2. Fields or application with approximate breakdown

(a) closed system

- — industries ....
- — farmers and skilled trades ....
- — use by the public at large ....

(b) open system

- — industries ....
- — farmers and skilled trades ....
- — use by the public at large ....

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Overall production and/or imports in order of tonnes per year 1; 10; 50; 100; 500; 1 000 and 5 000

— first 12 months ....tonnes/year

— thereafter ....tonnes/year

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2, expressed as a percentage

— first 12 months ....

— thereafter ....

2.3. Recommended methods and precautions concerning:

2.3.1. handling ....

2.3.2. storage ....

2.3.3. transport ....

2.3.4. fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. other dangers, particularly chemical reaction with water

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons
(e.g. poisoning)

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.1. Melting point

..................................°C

3.2. Boiling point

.... °C .... Pa

3.3. Relative density

.... (D_4^{20})

3.4. Vapour pressure

.... Pa at .... °C

.... Pa at .... °C

3.5. Surface tension

.... M/m (.................................. °C)

3.6. **Water solubility**

.... mg/litre (.............................. °C)

3.7. **Fat solubility**

Solvent — oil (to be specified)

.... mg/100 g solvent (.............................. °C)

3.8. **Partition coefficient**

n-octanol/water

3.9. **Flash point**

.... °C ☐ open cup ☐ closed cup

3.10. **Flammability** (within the meaning of the definition given in Article 2 (2) (c), (d) and (e))

3.11. **Explosive properties** (within the meaning of the definition given in Article 2 (2) (a))

3.12. **Auto-flammability**

.... °C

3.13. **Oxidizing properties** (within the meaning of the definition given in Article 2 (2) (b))

4. TOXICOLOGICAL STUDIES

4.1. Acute toxicity

4.1.1. Administered orally

LD_{50}.............................. mg/kg

Effects observed, including in the organs ....

4.1.2. Administered by inhalation

LC_{50}.............................. (ppm) Duration of exposure .... hours

Effects observed, including in the organs ....

4.1.3. Administered cutaneously (percutaneous absorption)

LD_{50}.............................. mg/kg

Effects observed, including in the organs ....

4.1.4. Substances other than gases shall be administered via two routes at least, one of which should be the oral route. The other route will depend on the intended use and on the physical properties of the substance.

Gases and volatile liquids should be administered by inhalation (a minimum period of administration of four hours).

In all cases, observation of the animals should be carried out for at least 14 days.

Unless there are contra-indications, the rat is the preferred species for oral and inhalation experiments.

The experiments in 4.1.1, 4.1.2 and 4.1.3 shall be carried out on both male and female subjects.

4.1.5. Skin irritation

The substance should be applied to the shaved skin of an animal, preferably an albino rabbit.

Duration of exposure .... hours

4.1.6. **Eye irritation**

The rabbit is the preferred animal.

Duration of exposure .... hours

4.1.7. **Skin sensitization**

To be determined by a recognized method using a guinea-pig.

4.2. **Sub-acute toxicity**

4.2.1. **Sub-acute toxicity (28 days)**

Effects observed on the animal and organs according to the concentrations used, including clinical and laboratory investigations ....

Dose for which no toxic effect is observed ....

4.2.2. A period of daily administration (five to seven days per week) for at least four weeks should be chosen. The route of administration should be the most appropriate having regard to the intended use, the acute toxicity and the physical and chemical properties of the substance.

Unless there are contra-indications, the rat is the preferred species for oral and inhalation experiments.

4.3. **Other effects**

4.3.1. Mutagenicity (including carcinogenic pre-screening test)

4.3.2. The substance should be examined during a series of two tests, one of which should be bacteriological, with and without metabolic activation, and one non-bacteriological.

5. ECOTOXICOLOGICAL STUDIES

5.1. **Effects on organisms**

5.1.1. Acute toxicity for fish

LC$_{50}$.............................. (ppm) Duration of exposure determined in accordance with Annex V (C)

Species selected (one or more) ....

5.1.2. Acute toxicity for daphnia

LC$_{50}$.............................. (ppm) Duration of exposure determined in accordance with Annex V (C)

5.2. **Degradation**

- biotic
- abiotic

The BOD and the BOD/COD ratio should be determined as a minimum

6. POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS

6.1. **For industry/skilled trades**

6.1.1. Possibility of recovery ....

6.1.2. Possibility of neutralization ....

6.1.3. Possibility of destruction:

- controlled discharge ....
- incineration ....

— water purification station ....

— others ....

6.2. **For the public at large**

6.2.1. Possibility of recovery ....

6.2.2. Possibility of neutralization ....

6.2.3. Possibility of destruction:

— controlled discharge ....

— incineration ....

— water purification station ....

— others ....

The effects which would indicate the need for such a study could include for example:

(a) serious or irreversible lesions;

(b) a very low or absence of a 'no effect' level;

(c) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous.

— Additional mutagenesis studies (including screening for carcinogenesis)

A. If results of the mutagenesis tests are negative, a test to verify mutagenesis and a test to verify carcinogenesis screening are obligatory.

If the results of the mutagenesis verification test are also negative, further mutagenesis tests are not necessary at this level; if the results are positive, further mutagenesis tests are to be carried out (see B).

If the results of the carcinogenesis screening verification test are also negative, further carcinogenesis screening verification tests are not necessary at this level; if the results are positive further carcinogenesis screening verification tests are to be carried out (see B).

B. If the results of the mutagenesis tests are positive (a single positive test means positive), at least two verification tests are necessary at this level. Both mutagenesis tests and carcinogenesis screening tests should be considered here. A positive result of a carcinogenesis screening test should lead to a carcinogenesis study at this level.

Ecotoxicology studies

— An algal test: one species, growth inhibition test.

— Prolonged toxicity study with Daphina magna (21 days, thus study should also include determination of the 'no-effect level' for reproduction and the 'no-effect level' for lethality).

The conditions under which this test is carried out shall be determined in accordance with the procedure described in Article 21 in the light of the methods laid down in Annex V (C) for acute toxicity tests with Daphnia.

— Test on a higher plant.

— Test on an earthworm.

— Prolonged toxicity study with fish (e.g. Oryzias, Jordanella, etc.; at least a period of 14 days; thus study should also include determination of the 'threshold level').

The conditions under which this test is carried out shall be determined in accordance with the procedure described in Article 21 in the light of the methods adopted under Annex V (C) for acute toxicity tests with fish.

— Tests for species accumulation; one species, preferably fish (e.g. Poecilla reticulata).

— Prolonged biodegradation study, if sufficient (bio)degradation has not been proved by the studies laid down in Annex VII, another test (dynamic) shall be chosen with lower concentrations and with a different inoculum (e.g. flow-through system).

In any case, the notifier shall inform the competent authority if the quantity of a substance placed on the market reaches a level of 100 tonnes per year or a total of 500 tonnes.

On receipt of such notification and if the requisite conditions are fulfilled, the competent authority, within a time limit it will determine, shall require the above tests to be carried out unless in any particular case an alternative scientific study would be preferable.

LEVEL 2

If the quantity of a substance placed on the market by a notifier reaches 1 000 tonnes per year or a total of 5 000 tonnes, the notifier shall inform the competent authority. The latter shall then draw up a programme of tests to be carried out by the notifier in order to enable the competent authority to evaluate the risks of the substance for man and the environment.

The test programme shall cover the following aspects unless there are strong reasons to the contrary, supported by evidence, that it should not be followed:

- chronic toxicity study,
- carcinogenicity study,
- fertility study (e.g. three-generation study); only if an effect on fertility has been established at level 1,
- teratology study (non-rodent species) study to verify teratology study at level 1 and experiment additional to the level 1 study, if effects on embryos/foetuses have been established,
- acute and sub-acute toxicity study on second species: only if results of level 1 studies indicate a need for this. Also results of biotransformation studies and studies on pharmacokinetics may lead to such studies,
- additional toxicokinetic studies.

Ecotoxicology

- Additional tests for accumulation, degradation and mobility.

  The purpose of this study should be to determine any accumulation in the food chain.

  For further bioaccumulation studies special attention should be paid to the solubility of the substance in water and to its n-octanol/water partition coefficient.

  The results of the level 1 accumulation study and the physiocochemical properties may lead to a large-scale flow-through test.
- Prolonged toxicity study with fish (including reproduction).
- Additional toxicity study (acute and sub-acute) with birds (e.g. quails): if accumulation factor is greater than 100.
- Additional toxicity study with other organisms (if this proves necessary).
- Absorption — desorption study where the substance is not particularly degradable.

ANNEX IX

A. PROVISIONS RELATING TO CHILD-RESISTANT FASTENINGS: for the record

B. PROVISIONS RELATING TO TACTILE WARNINGS OF DANGER: for the record

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FOOTNOTES

(1) Council Directive of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (79/831/EEC), OJ L259 of 15.10.79, p. 14.

(2) Council Directive on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC), OJ Nr. 196 of 16.8.67, p. 1.

(3) The Council of Ministers is composed of the relevant ministers of the Member States for the particular legislative proposal. Council Directives based on Article 100 of the Treaty of Rome such as the 6th Amendment must be adopted unanimously.

(4) For a review of the OECD's work on the field of chemical policies see : Managing Chemicals in the'80s, Organisation for Economic Co-operation and Development (Paris : 1982).

(5) Council Directive of 24 June 1982 on the major-accident hazards of certain industrial activities (82/501/EEC), OJ L230 of 5.8.82, p. 1.

(6) Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.(76/769/EEC), OJ L262 of 27.9.1976, p. 201. This directive has been used to regulate PCBs, PCTs, and monomer vinyl chloride; trichloroethylene, tetrachloroethylene, carbon tetrachloride and Tris; benzene; and substances used as fire retardants and in sneezing powder.

(7) "Approaches for Developing Testing Guidelines Under the Toxic Substances Control Act," The Conservation Foundation (Washington, DC : 1978) unpublished.

(8) See, for example, Chemicals in the Environment, Proceedings, International Symposium 18-20 October 1982, Copenhagen, Denmark.

(9) A broad comparison of the approaches adopted in TSCA and the 6th Amendment can be found in Public Policies for Chemicals, National and International Issues, Sam Gusman, Konrad von Moltke, Frances Irwin, Cynthia Whitehead (Washington, DC : 1980) pp. 57-77.

(10) Aide Memoire of 22 September 1978, EPA Preliminary draft guidance for premanufacture notification under TSCA.

Aide Memoire of 26 October 1978, Further comments on TSCA guidance for premanufacture notification (draft document of 12 September 1978).

Aide Memoire of 19 March 1979, Comments of the European Community on the proposed rules for TSCA section 5 (Fed. Reg. vol. 44, p. 2242 sqq, 10.1.79).

The Conservation Foundation
1717 Massachusetts Avenue, N.W., Washington, D.C. 20036
Telephone (202)797-4300 Cable CONSERVIT

November 1, 1983

The Honorable Dave Durenberger
Chairman
Subcommittee on Toxic Substances
& Environmental Oversight
Committee on Environment and
Public Works
United States Senate
Washington, D.C. 20510

Dear Senator Durenberger:

Enclosed are my responses to the questions attached to your October 5 letter. I appreciate the opportunity to provide these additional comments to you.

Sincerely,

J. Clarence Davies
Executive Vice President

Enclosure

QUESTIONS FOR DR. J. CLARENCE DAVIES
THE CONSERVATION FOUNDATION

1. One of the concepts behind the enactment of TSCA was that its various information gathering authorities, including test rules and the reporting authorities in section 8, could be used to support other programs in EPA and even in other agencies.

- Do you think that TSCA can be used in this way?
- Has EPA made adequate use of these authorities?
- If you think TSCA could be used more effectively in this way, please be specific about how particular provisions of TSCA could be used.

2. During the debate about TSCA in the mid-1970's, what did you see as the likely paths the program would take? Specifically, did you anticipate the track record that we now have regarding section 4 testing, new chemical data, and section 6 regulation? If you expected more of the program, what, in your opinion, are the most important factors that account for the actual pace of implementation?

3. Two claims have been made repeatedly about the TSCA premanufacture notification program: (1) that existing notice requirements already are sufficiently expensive that they are stifling innovation, and (2) that PMN data are too scanty to support reasoned risk assessment and that more -- not less -- information should be required.

What to you think about the merits of each of these statements? Is there any way to restructure the PMN program to resolve the apparent conflict between them?

November 1, 1983

RESPONSES OF J. CLARENCE DAVIES TO SENATOR DURENBERGER'S QUESTIONS ON TSCA

1. There is no doubt that the information gathering authorities contained in TSCA can and should be used to support other programs, both in EPA and other agencies. No other federal statute contains such powerful tools for obtaining test data, production and use information, and information on adverse effects from chemicals. This type of information is desperately needed for adequate regulation, both under TSCA and under many other statutes.

In general, EPA has not made adequate use of these authorities, as illustrated by the absence of any final testing rules and the inadequacy of the information submitted on PMNs for new chemicals. Within the existing framework of TSCA, the two most important steps that EPA can take are more vigorous and systematic use of section 5(e) and promulgation of final testing rules.

2. As I testified to your committee, the pace of implementation of TSCA has been very disappointing. The act has tremendous potential to make federal regulation of toxics both more rational and more effective, but this potential has largely gone unfulfilled. There have been no final section 4 testing rules, information on new chemicals is woefully inadequate, and the only chemicals that have been regulated in any serious way under section 6 are PCBs.

There are many factors that account for the slow pace of implementation. In my opinion, the three major ones are the inherent complexity of dealing with toxic substances, the timidity of EPA in exercising its authorities under the act, and the opposition of some segments of the chemical industry to effective regulation.

3. The charges that the PMN program is stifling innovation are based largely on a set of faulty studies. All of the studies are methodologically unsound because they attempt to establish a pre-1976 baseline for the number of new chemicals, but the data simply are not available (and never will be) to establish such a baseline. The studies suffer from a number of other problems as well. For example, the A.D. Little study done in 1978 for EPA, which is still widely quoted by industry officials, based its key economic analysis on a non-random sample of seven chemicals and then extrapolated these data to represent the entire chemical industry. The problems with the report were sufficiently great to be the subject of several days of Congressional hearings.

In considering the effect of TSCA on innovation two facts are of primary relevance. First, the number of PMNs submitted annually is large and has been increasing steadily. The current rate of more than 1,200 new chemicals a year is approximately equal to the number of new chemicals that industry estimated were manufactured annually before TSCA was enacted. Second, the cost of filing a PMN is small ($2-7,000 depending on the chemical and other factors) and is insignificant for the large volume chemicals that constitute a large portion of the PMN submissions. For very small volume specialty chemicals, the PMN filing costs may be a deterrent to innovation in some cases. Some form of low-volume exemption should be promulgated, and such an exemption should take care of this deterrent effect.

The evidence that the PMN data are too scanty to support reasoned risk assessment is overwhelming. Only 10% of new chemicals which are proposed for use by the general public contain any information on chronic toxicity, and even the data in that 10% usually consist only of an Ames test. Only 5% of the PMNs contain information on biological accumulation or degradation, one of the most important things to know about a chemical when doing a risk assessment. The whole OTA report on the PMNs is a catalogue of reasons why EPA does not have enough information to reasonably assess the risks of new chemicals.

If thorough testing were required for all new chemicals, resources would be wasted and innovation probably would be impeded. The solution consists of three elements: 1) a sensible exemption rule; 2) testing requirements for the non-exempted chemicals; 3) sufficient flexibility in the requirements so that they reasonably can be tailored to individual chemicals, based on scientific, not economic considerations.

National Coalition Against the Misuse of Pesticides
530 7th Street, S.E. • Washington, D.C. 20003 • 202/543-4313

November 10, 1983

The Honorable Dave Durenberger
Chairman
Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment and Public Works
U.S. Senate
Washington, D.C. 20510

Dear Senator Durenberger:

We appreciate the opportunity to respond to the questions you sent us as a follow-up to our testimony before your Subcommittee on August 1, 1983.

1.a. Question: Do you believe the increase in temporary registrations will adversely affect the environment?

Response: We are greatly concerned about the increase in section 18 and 24(c) registrations, because we believe that this increase poses a real and substantial threat to public health and the environment. There exists today a major problem with both the quality and quantity of data used for registering pesticides currently on the market. The emergency exemption and special local need (SLN) provisions, as currently constructed under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), allow for the expanded use of pesticides that are untested, have not been fully tested or have been registered with faulty or fraudulent data.

As was noted in our written testimony, the Rural Advancement Fund/National Sharecroppers Fund (RAF/NSF) found that more than 40 percent of all SLN pesticides registered in the past two years contain chemicals registered on the basis of invalid or fraudulent tests conducted by Industrial Bio-Test Laboratories, Inc. (IBT). According to the report, IBT conducted the safety tests for the three most widely used SLN pesticides (Furadan, Sencor and Paraquat). These products received a total of 361 SLNs for 25 states in 1981-82. The figures are based on a sample of 2,089 SLNs for 25 states (79 percent of all SLNs granted in 1981-82). I have attached a copy of the RAF/NSF report (A Report on "Special Local Need" Pesticide Registrations, Section 24(c) of FIFRA, Allen Spalt, Rural Advancement Fund, 1983) which I ask be introduced into the hearing record. 1/

In addition to the incidence of invalid data, there are widespread data gaps among Section 18 and 24(c) registered pesticides. As a result of this problem, most pesticide products in

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1/ Retained in committee files.

use today remain on the market even though they have not been fully tested for safety. As was pointed out in our testimony, a Staff Report on the EPA Pesticide Regulatory Program, prepared by the House Subcommittee on Department Operations, Research and Foreign Agriculture, revealed that between 79 and 84 percent of the pesticide products on the market have not been adequately tested for cancer, 90 to 93 percent remain inadequately tested for genetic damage, 60 to 70 percent are not fully tested for birth defects and 30 to 46 percent for reproductive hazards.

We have pointed out that the public is inadequately protected under the full and conditional registration programs of Section 3, FIFRA. Section 18 and 24(c) registrations only magnify this problem, resulting in the proliferation of inadequately tested pesticide products.

Finally, as the House Staff Report says quite clearly, "Pesticide registrations granted through sections 18 and 24(c) almost always entail significantly less complete and rigorous data requirements and scientific reviews." (page 114.)

1.b. Question: How can EPA operate more effectively to fully register and approve pesticide products to meet the regional or national needs of our agricultural community, consistent with full protection of public health and the environment.

Response: One of the primary shortcomings of EPA's operation to date stems from the public health and environmental threats associated with faulty data and data gaps --problems augmented by the huge increase and overuse of FIFRA's emergency and special local need exemptions. It has become apparent that the Section 18 and 24(c) provisions of FIFRA are being misused as a way to avoid or circumvent Section 3 registrations.

The RAF/NSF study cited above found that 90 percent of the SLN registrations studied are obtained by chemical manufacturers. Five companies received 47 percent of all SLNs in 1981-1982.

One way to avoid this situation is to forbid chemical companies and government institutions, such as USDA and state departments of agriculture, from applying for SLNs. Only users and their organizations should be able to request SLNs based on extraordinary local need.

Moreover, SLN permits are being issued for uses that are not, in fact, local in nature. The pest problems often being attacked are actually regional or national in scope. RAF/NSF found that a majority of SLN registrations were issued for major crops uses over a wide geographic area. More than 60 percent of all SLNs were issued for use on 10 major crops.

For example, 97 SLNs were obtained to control nematodes on soybeans in 14 states. In 9 states, SLNs were obtained for control of broadleaf weed sicklepod. According to the report, "Mosquitoes are not a local problem. Yet, 25 SLN registrations were approved in 10 states for mosquito control. Flies around livestock are another general problem. But state authorities granted and the EPA approved 184 exemptions to control flies on livestock and premises in 24 of the states studied." (RAF/NSF Report, page 5.)

In a March 16, 1983 letter to Congressman Dan Glickman, the former Assistant Administrator for Pesticides and Toxic Substances, John Todhunter, said, "We agree with your constituents that there are some cases in which a significant pattern of identical SLN registrations suggests that federal registration would be more appropriate." At this point, I ask that you introduce in the record the correspondence with the group that raised this issue in Kansas, Kansans for Safe Pest Control. 1/

In his letter to Congressman Glickman, Dr. Todhunter continued, "It is likely that we will evaluate "significant patterns" of identical SLN registrations on a case-by-case basis, rather than assigning an arbitrary number of state registrations as a basis of EPA response." However, from our point of view the problem needs a much broader response to ensure the protection of public health and environmental quality.

It appears that EPA does not have actual information on the process a state goes through to determine that a "special local need" really exists. EPA appears to simply "rubber stamp" SLNs and not investigate whether the uses are truly local in nature or whether the public is protected from unreasonable adverse effects. The same appears to be true for emergency exemptions issued.

In general, we propose to require stricter scrutiny and higher standards of public health protections for Section 18 and 24(c) registrations. Both proposals include a public participation component which will enable greater public oversight.

1/ Retained in committee files.

We are attaching two relevant sections from our briefing package on the Federal Insecticide, Fungicide and Rodenticide Reform Act, H.R. 3818 and S. 1774, called Getting the Bugs Out Of FIFRA. These sections outline amendments concerning Sections 18 and 24(c) of FIFRA. We would appreciate their inclusion in the hearing record. We believe that these amendments will go a long way in remedying the dangerous federal practices which today allow pesticide products to escape full and accurate testing. At the same time, we believe that under real emergencies and actual special local need problems, the agricultural community will have access to the pesticides they may need, if these provisions were to be enacted.

2. Question: Mr. Robert Dawson, Wisconsin Public Intervenor, testified that seven pesticides have been found in Wisconsin's groundwater. Other evidence indicates that this is not an isolated case. What explains such widespread environmental contamination in spite of FIFRA's extensive data requirements, applicator certification and other safeguards?

Response: It is instances such as the one you cite regarding Wisconsin's groundwater which strengthen our membership's resolve to strengthen FIFRA. Once again, the problem, at least in part, is inadequate premarket product testing --in this case, testing which did not take into account the possibility of groundwater contamination.

We have attached our section analysis and proposed statutory amendment to improve groundwater protection. It is contained in Section 4(b) of H.R. 3818 and S. 1774 and seeks to amend the provisions pertaining to classification of pesticides under Section 3(d) of FIFRA. Please note that in the proposed amendment the Administrator is directed in all decisions pertaining to classification to consider the potential contamination of groundwater. It has turned out, over and over again, that EPA did not anticipate groundwater problems and therefore did not test for it.

The "extensive date requirements, applicator certification and other safeguards" which you mention, unfortunately are not extensive nor do they ensure safety. First, as we have stated, all too often pesticide products have been registered under an exemption provision which allow them to slide by without careful screening. Second, and as important, we have noted in our written testimony that applicator certification provisions of FIFRA are inadequate. We direct your special attention to the July, 1983 GAO report Better Coordination Is Needed Between Pesticide Misuse Enforcement Programs and Programs for Certifying and Training Individuals to Apply Pesticides (GAO/RCED-83-169). Interestingly, this report highlights problems and inadequacies with certification and training in your own state of Minnesota.

Third, because of another loophole in FIFRA, those handling toxic pesticides may not actually be trained. Untrained individuals must simply apply the pesticide "under the supervision" of a certified applicator. Unfortunately, interpretation of this phrase has resulted in untrained people, without on-site supervision, harming themselves and the environment. The prudent response, we believe, is to ensure that all restricted use pesticides are applied by applicators trained under an upgraded training program. I have attached a copy of several amendments in H.R. 3818 and S. 1774 to improve this aspect of the law. Section 3(b) and 4(b)(1)(C) of the bill ensure that applicators of restricted use pesticides are trained and certified and Section 5 upgrades the actual training program.

Finally, widespread contamination can be directly linked back to FIFRA's overall standard of safety. H.R. 3818 and S. 1774 seek to incorporate into FIFRA the "will endanger" standard of the Clean Air Act's Section 211. This definitional change will better protect against contamination than the current benefit risk analysis contained in FIFRA. I have attached this simple change as contained in Section 3(d) of the bill, although it appears elsewhere throughout the legislation as well.

What we are suggesting here we believe to be only a step in the right direction. I believe that we must carefully follow developments in Wisconsin and other states, use the experience and responses in those states to immediately begin to craft a comprehensive national groundwater protection strategy with particular emphasis on pesticides.

Thank you for the opportunity to comment on these matters. We look forward to working with you and urge you to consider cosponsoring S. 1774 as part of an effort to improve the protections from pesticides afforded the public.

Sincerely,

Jay Feldman

Jay Feldman
National Coordinator

encls.

I. Closing the "Emergency Exemption" Loophole.

The proposed amendments to Section 18 are designed to provide a legislative remedy to the well-documented and widespread abuse of this provision. As noted in the House Agriculture Subcommittee, December, 1982, Staff Report entitled EPA Pesticide Regulatory Study (p. 35), sections 18 and 24(c) of FIFRA provide registrants an opportunity to circumvent the exclusive use and data compensation provisions of section 3. In 1978, 165 section 18 exemptions were granted. In 1982, 727 were granted, representing a 4.4-fold increase.

Proponents of the reregistration of Compound 1080 are using the Emergency Exemption section in an effort to use the chemical before a Section 3 registration is granted. At least four states (Wyoming, Montana, South Dakota, and Idaho) and possibly a fifth (Utah), have filed requests for emergency exemptions. Attempts to use the emergency exemption requirement to allow use of ferriamicide (mirex) to kill fire ants were halted by a federal district court in the fall of 1982.

The amendments specify criteria that the Administrator must use in granting emergency exemptions and provide for notice and public comment. Finally, the Administrator's decision must be supported by the public record.

Section 12 of this Act extensively amends the "Emergency Exemption" provision contained in section 18 of FIFRA. The Administrator is authorized to grant an exemption to a state or federal agency from the provisions of FIFRA when such an exemption is necessary to prevent or substantially mitigate an imminent and substantial danger to public health or welfare. An exemption for a use of a pesticide may not be granted if there is an efficacious registered pesticide available to fill the pest control need for which the exemption is sought, or if an alternative pest control technology is available.

Subsection 12(c) of this Act limits the time period for an emergency exemption to one year, and allows for no more than two renewals.

Subsection 12(g) of this Act states that in no case may section 18 of FIFRA authorize an unregistered use of a pesticide without the prior approval of the Administrator. In extraordinary emergencies, the Administrator must act on an application for an emergency exemption within 48 hours of receipt. (See page 47)

FIFRA Sec. 18*

"SEC. 18. EXEMPTION OF FEDERAL AGENCIES.

"The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption.

"The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination."

*See Public Participation Section (IV) for two additional amendments to FIFRA Sec. 18

H.R. 3818 Sec. 12

EXEMPTION OF FEDERAL OR STATE AGENCIES

Sec. 12. Section 18 (7 U.S.C. 136p) is amended to read as follows:

"Sec. 18. Exemption of Federal or State Agencies.

"(a) Requests.—A Federal or State agency may request the Administrator to exempt the agency from any provision of this Act in accordance with this section.

"(b) Exemptions.—

"(1) Except as provided in paragraph (2), the Administrator may grant a requested exemption if the Administrator determines that the exemption is necessary to prevent or substantially mitigate an imminent and substantial danger to public health or welfare.

"(2) The Administrator may not grant an exemption which would permit the sale or distribution of a pesticide for a use for which it is not registered under this Act if—

"(A) another pesticide is registered under this Act for that use, unless the applicant for the emergency exemption demonstrates that the registered pesticide is ineffective or cannot be made available for that use;

"(B) the Administrator determines that there is another pest control practice which could be used for the same purpose and would produce a less detrimental effect on the public health, welfare, or environment. For the purposes of this subsection, the term "pest control practice" including both a means of controlling a pest without using a pesticide, and the use of a pesticide which is registered for another use or uses.

"(c) Length and Renewal.—An exemption under this section may not be issued for more than one year or renewed more than twice.

"(d) Consultation.—In determining whether to grant an exemption under this section, the Administrator may consult with appropriate State or Federal officials, including those with responsibilities in areas such as agriculture, public health, and fish and wildlife protection.

J. Special Local Needs Registrations Limited to Special Local Needs

A recent report to the House agriculture operations subcommittee demonstrates that pesticide companies have widely abused the special local needs registration program to market pesticides throughout the country, state by state, as special local needs. This end-run enables them to avoid meeting the federal testing requirements under Section 3(c). This bill requires strict agency scrutiny of 24(c) registrations, and requires veto of such registrations where they are not special and local. It creates a negative rebuttable presumption that is triggered when five or more state registrations have been obtained. These registrations will expire automatically after five years and may be reissued by the state.

The statute currently provides that the Administrator "may" suspend state authority if it fails to exercise adequate controls. The amendment would require the Administrator to do so.

Section 24(c) of FIFRA is amended to refer to "pesticides which are registered under paragraph (5) or 7(A) of section 3(c)..." rather than to "federally registered pesticides...". The effective date for a registration under section 24(c) is changed to ninety days after the date on which the Administrator is notified by a state of the state's intention to issue the registration, assuming the Administrator does not disapprove the use during the ninety day period. The clause prohibiting the Administrator from disapproving a section 24(c) registration on the grounds of a lack of essentiality is eliminated. The Administrator is also authorized to deny a section 24(c) registration if the pesticide use is unnecessary to meet special local needs. The Administrator's discretion to disapprove a special local need registration that is inconsistent with the Federal Food, Drug, and Cosmetic Act is eliminated by changing "may immediately disapprove the registration" to "shall immediately disapprove...".

Subsection 16(b)(3)(D) specifies that a rebuttable presumption shall arise and that a special local need for a pesticide does not exist if five or more states seek the same pesticide for the same special local need. The discretion of the Administrator to suspend the authority of a state to issue registrations under section 24(c) is eliminated when the Administrator determines a state is not capable of exercising adequate controls to assure that state registrations are granted in accordance with the provisions of FIFRA. This change is brought about by changing "may suspend the authority" to "shall suspend...".

FIFRA Sec. 24(c)

"SEC. 24. AUTHORITY OF STATES.

"(a) A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

"(b) Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.

"(c)(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or cancelled by the Administrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize distribution and use only within such State.

H.R. 3818 Sec. 16(b)

AUTHORITY OF STATES

Sec. 16. (a) Section 24(b) (7 U.S.C. 136v(b)) is amended—

(1) by striking out "Such" and inserting in lieu thereof "(1) Except as provided in paragraph (2), the"; and

(2) by adding at the end thereof the following new paragraph:

"(2) A State may impose or continue in effect requirements for labeling or packaging in order to enforce a prohibition on the use of a federally registered pesticide or device in the State. If a State imposes or continues in effect the requirements, the State shall require that the prohibited use be stated on the labeling or packaging and shall notify the Administrator of the action and the reasons for the action. The Administrator shall keep a record of the requirements and make the record available to the public.".

(b) Section 24(c) (7 U.S.C. 136v(c)) is amended—

(1) by striking out "federally registered pesticides" in the first sentence of paragraph (1) and inserting in lieu thereof "pesticides which are registered under paragraph (5) or (7)(A) of section 3(c) and";

FIFRA Sec. 24(c) (continued)

"(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

"(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act that permits the residues of the pesticide on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

"(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 25 of this Act, that a State is not capable of exercising adequate controls to assure that State registration under this station will be in accord with the purposes of this act or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.".

H.R. 3818 Sec. 16(b) (continued)

(2) in paragraph (2)—

(A) by striking out "for more than ninety days if disapproved by the Administrator within that period" in the first sentence and inserting in lieu thereof "until ninety days have elapsed after the date on which the Administrator is notified by a State of the intent of the State to issue the registration";

(B) by inserting after the first sentence the following new sentence: "If the Administrator disapproves the registration during the ninety day period, the registration shall not become effective."; and

(C) by striking out "(A) on the basis of lack of essentially of a pesticide or (B)" in the last sentence;

(3) in paragraph (3)—

(A) by striking out "or" in the second sentence and inserting in lieu thereof "that";

(B) by inserting after "hazard," in the second sentence the following: "or that the registration is unnecessary to meet special local needs and therefore the registrant should apply for registration under section 3(c)(5),";

(C) by striking out "may" in the second sentence and inserting in lieu there of "shall"; and

(D) by adding at the end thereof the following new sentence: "If more than five States provide under this subsection for the registration of a new or additional use of a pesticide to meet the same special local need, there shall be a rebuttable presumption that a special local need does not exist for purposes of this subsection.";

(4) by striking out "may" in the first sentence of paragraph (4) and inserting in lieu there of "shall"; and

(5) by adding at the end thereof the following new paragraphs:

"(5) A registration issued by a State under this subsection shall expire after a five-year period. At the end of each five-year period, the State may issue a new registration in accordance with this subsection.

"(6) If a special local need registration has not been used, or has lapsed, the State authority initially granting the registration must so inform the Administrator.".

C. Strengthens Environmental Protections and Specifically Groundwater Protections.

Subsection 4(b) of H.R. 3818 amends the provisions pertaining to classification of pesticides under section 3(d) of FIFRA. The Administrator may classify a pesticide for general use when it "will cause unreasonable adverse effects..." rather than when it "will generally not cause...". The Administrator is further directed in all decisions pertaining to classification to consider the potential contamination of groundwater in determining whether a pesticide should be classified for restricted use.

FIFRA Sec. 3(d)(1)(B),(C)&(C)(ii)	H.R. 3818 Sec. 4(b)(1)(A), (B),(D)&(E)
"(d) *Classification of Pesticides.*— "(1) *Classification for general use, restricted use, or both.*— "(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, he will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use. "(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, he shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use: "(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination	(b) Section 3(d) (7 U.S.C. 136a(d)) is amended— (1) in paragraph (1)— (A) by striking out "generally" in subparagraph (B); (B) by inserting "or contamination of ground water," after "applicator," in the matter preceding clause (i) of subparagraph (C); (D) by inserting "(including contamination of ground water)" after "environment" in the first sentence of subparagraph (C)(ii); and (E) by inserting after the first sentence of subparagraph (C)(ii) the following new sentence: "In establishing such other restrictions, the Administrator shall specifically consider the seasonal, soil-specific, and hydrogeologic characteristics of the location in which the pesticide will be applied."; and
"(2) *Change in classification.*—If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, he shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 6(b).	(2) by inserting "(including contamination of ground water)" after "environment" in the first sentence of paragraph (2). . . .

B. Actual Applicator of Restricted Use Pesticides Must Be Certified. (See also III F. below.)

Current law requires applicators of "restricted" (more toxic) pesticides to be certified. It allows non-certified persons to actually apply the pesticides while "under the supervision" of the certified applicator, although the certified applicator need not even be present at the application site. This amendment strikes the indirect supervision loophole. Since the Act has permitted a very broad and simple certification process, the loophole can be removed without disruption.

Section 3 of H.R. 3818 changes the definitions of "certified," "private" and commercial" applicators. In all three cases, a clause is eliminated that allows a certified applicator to "supervise the use of" a restricted use pesticide applied by another person. The definition specifying what it means to apply a restricted use pesticide "under the direct supervision of a certified applicator" is deleted. Accordingly, all applicators of restricted use pesticides must be certified under the provisions of section 4 of FIFRA.

FIFRA Sec. 2(e)
Certified Applicator, Etc.

"(e) *Certified Applicator, Etc.*—

"(1) *Certified applicator.*—The term 'certified applicator' means any individual who is certified under section 4 as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or use dilutions of registered pesticides consistent with section 2(ee) of this Act, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this Act.

"(2) *Private applicator.*—The term 'private applicator' means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

"(3) *Commercial applicator.*—The term 'commercial applicator' means an applicator (whether or not he is private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

"(4) *Under the direct supervision of a certified applicator.*—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

H.R. 3818 Sec. 3(b)

(b) Section 2(e) (7 U.S.C. 136(e)) is amended—

(1) in paragraph (1)—

(A) by striking out "or supervise the use of" in the first sentence; and

(B) by striking out "use" in the second sentence and inserting in lieu thereof "uses";

(2) by striking out "or supervises the use of" each place it appears in paragraphs (2) and (3); and

(3) by striking out paragraph (4).

G. Applicator Training Program Upgraded.

This provision of H.R. 3818 strengthens the ability of the Administrator to regulate the certification of applicators by deleting limits on the Administrator's certification program and the certification form as alternative proof of qualification.

Section 5 of H.R. 3818 changes the requirements that must be met by persons seeking certification to apply restricted use pesticides. The amendment eliminates the existing clauses that prohibit a state from requiring a written examination as part of the certification process.

FIPRA Sec. 4(a)(1) Use of Restricted Use Pesticides; Certified Applicators.

"SEC. 4. USE OF RESTRICTED USE PESTICIDES; CERTIFIED APPLICATORS.

"(a) *Certification Procedure.*—

"(1) *Federal certification.*—In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides: *Provided*, That such program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish competency in the use of pesticides. Prior to the implementation of the program, the Administrator shall publish in the Federal Register for review and comment a summary of the Federal plan for applicator certification and shall make generally available within the State copies of the plan. The Administrator shall hold public hearings at one or more locations within the State if so requested by the Governor of such State during the thirty days following publication of the Federal Register notice inviting comment on the Federal plan. The hearings shall be held within thirty days following receipt of the request from the Governor. In any State in which the Administrator conducts a certification program, the Administrator may require any person engaging in the commercial application, sale, offering for sale, holding for sale, or distribution of any pesticide one or more uses of which have been classified for restricted use to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may by regulation prescribe. Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification: *Provided, however*, That the certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by his completing a certification form. The Administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this Act, and may include in the form an affirmation that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by him.

H.R. 3818 Sec. 5

Sec. 5. Section 4(a)(1) (7 U.S.C. 136b(a)(1)) is amended—

(1) by striking out "and shall not require private applicators to take any examination to establish competency in the use of pesticides" in the proviso of the first sentence; and

(2) by striking out "; *Provided, however*" in the seventh sentence and all that follows through the end of the eighth sentence and inserting in lieu thereof a period.

D. Definition of "Unreasonable Adverse Effects on Man and the Environment" Changed To Distinguish Between Humans and the Environment.

Under current FIFRA, the operative standard for registration and cancellation is the prevention of unreasonable adverse effects on man and the environment. Under H.R. 3818 this will remain the test for pesticides that pose risks only to the environment. For pesticides that pose risks to human beings, the test will be the more stringent "will endanger" test taken from section 211 of the Clean Air Act as interpreted in Ethyl Corp. v. EPA, 541 F.2nd 1 (D.C. Cir. 1976). The "will endanger" test will allow EPA to act on the basis of risks alone without a strict comparison with benefits. Elsewhere in the bill, a "will endanger human health" standard is specified for adverse effects on man.

FIFRA Sec. 2 (bb) Unreasonable Adverse Effects on the Environment	H.R. 3818 Sec. 3(d)
"(bb) *Unreasonable Adverse Effects on the Environment.*—The term 'unreasonable adverse effects on the environment' means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.	**(d) Section 2(bb) (7 U.S.C. 136(bb)) is amended by striking out "man or".**

Natural Resources Defense Council, Inc.

122 EAST 42ND STREET
NEW YORK, N.Y. 10168
212 949-0049

January 19, 1984

Senator Dave Durenberger, Chairman
Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment & Public Works
United States Senate
Washington, D.C. 20510

Dear Senator Durenberger:

Following my testimony on behalf of NRDC at your hearings on Reauthorization of the Toxic Substances Control Act, you sent me a series of questions concerning the functioning and proper role of various provisions of the Act. My responses, which are set forth below, are in the order in which the questions were presented. I hope that you will find them useful.

1. §9 Relationship to Other Federal Laws

NRDC strongly disagrees with EPA's contention, presented in testimony, that TSCA regulatory authority under §6 applies "only if actions under other laws or by other Federal agencies are not forthcoming." As the legislative history of the Act clearly shows, the subject of deference to other statutes and to other agencies with jurisdiction over the subject matter, was hotly debated prior to the passage of TSCA. In fact, the House bill initially provided for mandatory referral where an agency other than EPA had jurisdiction over a particular problem. In order to resolve the dilemma and permit EPA to act in appropriate situations, even where another agency with arguable jurisdiction could have acted, the language of §9 of TSCA makes distinctly discretionary the determination whether EPA or another agency should act in the first instance. It makes no sense whatever to require EPA always to defer to another reglatory agency or another EPA office in cases where TSCA might apply, and yet achieve the clear purpose of §2(b)(2) of TSCA, which is to provide "adequate authority" to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment.

It is left to the discretion of the EPA Administrator to determine that a risk may be prevented or reduced to a sufficient extent by action taken under a federal law not administered by the EPA, or under an EPA statute other than TSCA. Only after the discretionary judgment is made must the Administrator then defer and not use the TSCA. However, if the Administrator makes the discretionary judgement that it is "in the public interest to protect against a risk under TSCA", or that TSCA is more appropriate than some other statute not administered by the EPA, then TSCA gives the EPA Administrator the full authority to go forward to protect against the particular risk. See Conference Report on the Toxic Substances Control Act, Legislative History of TSCA, pp. 697-698.

Clearly, if Congress intended TSCA to be a second-order statute, to be used only as a last resort when actions under other laws or by other agencies were "not forthcoming," it could have said so plainly. Instead, the legislative history demonstrates that the decision to use TSCA was left entirely within the EPA Administrator's discretion. There is no legislative direction to EPA to defer action in the first instance. On the contrary, the thrust of TSCA was and is to authorize EPA to act "to provide for the greatest possible measure of protection to health and the environment." TSCA Conference Report at 696. The purpose of §9 is to prevent duplicative actions in appropriate cases -- not to stay EPA's hand from addressing unreasonable risks until it is clear that no other action is forthcoming.

The Agency's performance in implementing TSCA has been very tentative and cautious, as their interpretation of §9 well indicates. To clarify that EPA's hands are not tied with respect to using TSCA where the Administrator believes a TSCA remedy would be effective, the House TSCA Reauthorization bill, H.R. 4304, would delete entirely the complex language of §9(a) as well as the second sentence of §9(b), and would substitute a requirement of appropriate notice to other agencies at least 20 days before EPA proposes to act under TSCA against an unreasonable risk. Such an amendment would emphatically restate the Congress' intention that EPA expeditiously address unreasonable risks under TSCA where the Administrator judges that such action is necessary. We strongly support this change and urge that a similar clarifying amendment be included in the Senate bill.

2. Use of Information Gathering Authorities

TSCA provides EPA with extensive information gathering authority in §§4, 8, 10, and 11. Section 10 in particular authorizes and directs the EPA, among other things, to design, establish and coordinate a toxicological data retrieval system for use by all Federal "and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment." To this end, EPA has spent many years developing the Chemical Substances Information Network (CSIN), a very comprehensive and valuable although not well-publicized data resource. TSCA also directs EPA to coordinate and conduct research (1) on screening techniques for carcinogenic, mutagenic, teratogenic and ecological effects of chemicals; and (2) on monitoring techniques and instruments for detection of toxic substances; and to establish basic research programs to develop the fundamental scientific bases for such screening and monitoring techniques. Finally, under §27 of TSCA the Secretary of the Department of Health and Human Services, in consultation with the EPA, is empowered to conduct and finance development and evaluation of new test methods for assessing chemical toxicity, persistence, and other characteristics which affect health and the environment.

How extensively EPA and HHS have utilized these authorities, and how effectively the TSCA information program is supporting the activities of other EPA programs and other regulatory agencies are questions that only a Congressional inquiry can answer. There may be greater exchange of data and information than has been made public. However, any exchange will necessarily be limited by statutory confidentiality protections and prohibitions that were investigated and described at length in a 1980 report by the interagency Toxic Substances Strategy Committee entitled, "Toxic Chemicals and Public Protection."

In short, it is difficult to comment on the effectiveness of EPA's use of TSCA-gathered information to support other EPA programs and other agencies' needs, when the extent of such use is not readily apparent to an outside observer. It does not appear, however, that §10 has been effectively implemented apart from development of CSIN, and the breadth of use of that system remains a question. For this reason, NRDC recommends that the Subcommittee investigate these issues further through oversight hearings or a GAO Report and take appropriate legislative action if necessary thereafter.

With regard to the Agency's use of its §8 powers, NRDC believes that EPA has been extremely cautious. Since §8 rules are time-consuming to promulgate, and tend to be used only in support of §4 and §6 regulatory authorities, the general dearth of regulatory activity over the past few years has resulted in relatively few §8 actions. Although there appears to be some activity now underway in the TSCA program that could lead to future §6 actions, our conclusion remains that §8 has been underutilized.

One activity that should occur in the foreseeable future would be updating the §8(b) chemical substances inventory, since production volumes and site information, inter alia, are presently very out-dated. The inventory was published in 1979, using 1977 data, and has not been updated since.

Two problems of great concern to outside users of toxic substances information are (1) the breadth of confidentiality protection which is currently provided under TSCA §14(a), and (2) the growing tendency of EPA, apparently in response to the Office of Management and Budget's implementation of the Paperwork Reduction Act, to reduce record-keeping requirements to a minimum and to specify that records be maintained in company files rather than reported periodically to the Agency, until, if ever, EPA asks to see them. The confidentiality problem was discussed in NRDC's testimony and will be addressed further in the next section. The second problem is also of extreme importance for public oversight of EPA's implementation and industry compliance with existing regulatory requirements and urgently warrants legislative attention. If compliance records are not reported periodically to EPA, they are inaccessible to the public, and access to that information and citizen enforcement under §20 of TSCA are completely defeated. While this may have been the intention of both OMB and the Agency in providing for maintenance of all compliance records in company files with no reporting to EPA, it contravenes the clear Congressional intent in TSCA that there be extensive public involvement in and oversight of EPA's implementation of the toxic substances control program. Among other changes that NRDC believes should be made in TSCA, a requirement that compliance records be reported periodically to EPA, ranks very high.

3. Confidentiality Protection Under TSCA

NRDC has testified that the broad scope of protection from disclosure on grounds of confidentiality provided for information submitted to EPA impedes public access to data and precludes participation in §5(a) PMN reviews. By accepting broad and unsubstantiated confidentiality claims in the first instance and relying on the Agency's time-consuming Freedom of Information Act confidentiality determination and appeal procedures, the 90-day PMN review period can expire before the validity of particular claims is resolved. To remedy this problem, the House amendments would stay the PMN clock until the issue has been decided, and the requested information is either finally withheld or else disclosed to the requester. While NRDC supports this approach, we also believe that further specific Congressional direction is needed to clarify which data may not be withheld from public disclosure on confidentiality grounds. In our view, information concerning the identity, use, disposal and environmental fate of new chemicals should be required to be disclosed so that meaningful assessments of potential health and environmental exposures can be made by members of the public. Under the present system, such information is routinely withheld from disclosure.

To protect manufacturers, NRDC believes that the current law's specification that manufacturing processes and mixture proportions -- matters which are traditionally legitimate subjects of trade secrecy protections -- are adequate. Where additional protection is sought, the burden of establishing the need for such protection should be borne by the applicant.

If the point of PMN review is to ascertain prior to manufacture the likely or possible adverse health and environmental risks of a new chemical, and the public is to be apprised of and invited to participate in this process, then data relevant to potential exposure to the substance must be disclosed along with available toxicity data. Chemical identity, volume, use, disposal, and environmental release information are all critical components of an exposure assessment and should be denied confidentiality protection by law. Since manufacture of new chemicals will in many cases lead to public exposure through drinking water, consumer products, employment and other routes, NRDC feels that there is a corresponding public right to know the potential magnitude and consequences of such exposure before it occurs. For new chemicals, pre-manufacture is the only point at which such questions can be answered without first experiencing human or environmental injury. That was the promise and purpose of the PMN sections of TSCA when it was enacted in 1976. The goal of identifying potential bad-actor chemicals before they enter commerce has not yet been achieved. The "safety net" the existing PMN program provides involves little hard data and many guesses, and falls far short of providing a reasonable degree of assurance to the public that chemicals entering commerce today will not cause serious health or environmental harm in the future.

NRDC does not believe that the identity of a chemical implicated in causing a serious toxic effect should ever be withheld from public disclosure. As a matter of public policy, the choice between protecting private property or public health should be resolved in favor of the latter in every instance. The application of this principle to §8(e) notices would require that they be made public insofar as they indicate that there is evidence that a chemical may pose a substantial risk of injury to health or the environment. A mechanism to guarantee that workers and others exposed to the chemical are expeditiously apprised of the potential risk, should also be considered for inclusion in the statute. Under current law, EPA's handling of §8(e) notices is left entirely to the Agency's discretion. Mandatory public disclosure of the contents of such notices would lessen the chance of their falling into a bureaucratic limbo, and would inform directly affected parties of the potential hazard.

4. Role of a §5(b)(4) "Risk List"

EPA's failure to implement §5(b)(4) of TSCA is both illustrative of the Agency's general difficulty in actively implementing TSCA, and indicative of a possible problem with the provision itself. NRDC's reading of the legislative history of TSCA is that §5(b)(4) was intended to apply primarily, although not exclusively, to existing chemicals rather than to new chemicals. Because it requires EPA to publish significant new use rules when substances are placed on the risk list, the Agency must evaluate existing and potential uses. Not only does this presuppose that there are some existing uses, but it also imposes on the Agency the burden of assessing future changes in volume, kind of use, magnitude of exposure, and manufacturing, distribution and disposal patterns and practices. The potential difficulties and magnitude of such an undertaking may in part explain the Agency's past reluctance to put the provision into effect.

In NRDC's opinion, §5(b)(4) should be implemented to control new uses of toxic substances such as asbestos and benzene, for example, which are currently under consideration for possible regulation. In addition, changes in production or use patterns of new chemicals approved on the basis of a particular use described in the PMN could be monitored effectively. We do not, however, see an immediate connection between the risk list and PMN testing. Were new chemicals testing keyed to presence on the risk list, EPA would have the impossible burden of anticipating and documenting the potential hazard of a new chemical and listing it in order to justify testing requirements. It is unclear to us whether or how such a system would work. As stated in NRDC's testimony, we favor a system of base set testing for all new chemicals not otherwise exempt from PMN requirements, to facilitate accurate PMN hazard assessments, and to generate the data that would support a rule placing a new chemical on the risk list for future significant new uses.

5. Evaluation of the Minimum Premarket Data Set

As requested, NRDC staff have rated the elements of the MPD on the suggested scale. Our rating and brief accompanying comments are attached. (See Attachment A). As was made clear in our testimony, NRDC does not favor legislating the European MPD into TSCA, although we do support enactment of a requirement that EPA devise a PMN data set for all new chemicals not otherwise exempt under §5(b)(4). The House bill has incorporated this concept into its proposed amendment to §5 and we urge your Subcommittee to seriously consider a similar approach.

Yours truly,

Jacqueline M. Warren

Jacqueline M. Warren
Senior Staff Attorney

ATTACHMENT A

Evaluation of Predictive Ability of OECD Minimum Pre-Market Data Set

Chemical Identification

This is, of course, necessary for any evaluation of a substance. This critical information is the biggest hurdle when trying to provide health care to a person exposed to a toxic substance. Information on impurities and additives is especially important. Structural formula should not be over emphasized -- structure-activity analyses are generally unrewarding.

Production/Use/Disposal

As above, critical to evaluation. Best if supplemented by exposure estimates and strict details with regard to disposal or decomposition. Along with this, the rationale for any precautions involved in its use should be well discussed.

Analytical Methods

Of course, absolutely necessary for any followup analysis or monitoring.

Physical/Chemical Data

Like the above categories, nothing contained herein will allow specific predictions of health effects. Their values are, however, as follows:

melting point - important for chemical fate, and ambient exposure data (inhalation possibility, etc.)

boiling point - as above.

density - high density liquids to bottom of water. Vapor pressure/volatility - important for exposure data. (inhalation).

solubility - determining content in water, etc. (exposure data).

partition coefficient - may correspond to known uptake, absorption as that is analogous to cell membranes' function.

adsorption-desorption - very important for toxics in water: can help determine amount of substance in silts etc. Good absorption to soils, less transport.

particle size - quite important in terms of distribution in lungs of substances that are inhaled.

dissociation constant - ionic status another important factor for admission of a substance through cell membranes.

hydrolysis - allows estimate of possible transformation. Would add tests for oxidizing properties. These would tend to indicate capacity for transformation within the body.

Acute Toxicity Data

These tests are in general good predictors for acute effects; they are poor to fair predictors of metabolic dysfunctions. They will not act as predictors with regard to the other promoters of interest. Nonetheless, they are vital as they will determine initial methods and rationales for avoiding exposures.

Repeated Dose Toxicity Data

These 14-28 days tests will allow analysis of dose-response with regard to major organ systems. As a result, they are poor to fair predictors of metabolic dysfunction (largely liver responses), neurotoxicity (if proper necroscopics performed), and reproductive dysfunction. Unfortunately, many organ system toxins will be overlooked, as chronic exposure is required for full development of dysfunction. Be this as it may, these kind of studies will guide further long term studies.

Degradation/Accumulation Data

This is another set of studies which cannot really predict health effects, but which is important for assessing the magnitude of any health effects that are noted. Note that OECD test battery includes fat solubility in bioaccumulation. In addition to the OECD battery it would be best to include information on reactivity with water and assessment of bioaccumulation of degradation products.

Mutagenicity Data

This is critical for assessment of the potential of a substance for carcinogenicity and feto-toxicity/mutation. Bacterial mutagenicity screening tests are easy to do, cheap, take about 3 days, and have good positive correlations with known carcinogens. See IARC Monograph, Long Term and Short Term Screening Assays for Carcinogens: A Critical Appraisal. (1980). A related test for DNA repair correlates well with carcinogenicity, and also represents a biological analogy with those birth defects that are based on spontaneous genetic abnormalities.

Mammalian cell line mutagenesis studies involving in vitro transformation studies, may be even better predictors of carcinogenicity in humans. Id. at p.114. Cytogenetic analysis in both drosophila and human lives is another close biological analogy to birth defects, as well as a prediction of carcinogenicity.

Thus, these types of tests are critical to initial testing and should, perhaps, be completed as a battery. They will then guide future research.

Ecotoxicity Data

Good for initial assessment, but do not act as predictors for human health.

Algae - good selection for test, as it is critical to energy system of body of water's ecosystem.

Daphnia - very sensitive - acts as an invertebrate indicator.

Fish LC_{50} - supplements LD_{50}

Neurotoxicity - difficult to gauge without chronic tests, but 28-day studies followed by necropsy important.

Behavior Abnormalities - no good short term test.

Cancer - battery of mutagenicity studies probably best way to go. Need followup with bioassays.

Birth defect - feto-toxicity best studied on short term basis with mutagenesis. Need long term animal studies.

Gene defects - not a coherent category of human illness.

Reproductive Dysfunction - as with feto-toxicity, some correlation with mutagenesis, but need longer animal studies.

Metabolic Dysfunction - 28-day studies plus acute toxicities important, and fair to good predictors.

Acute Effects - acute studies of a wide range are good predictors.